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85-619-CFX  
atus: GRANTED

Title: Merrell Dow Pharmaceuticals, Inc., Petitioner  
V.  
Larry James Christopher Thompson, et ux., et al.

cketed:  
tober 11, 1985

Court: United States Court of Appeals  
for the Sixth Circuit

Counsel for petitioner: Woodside III, Frank C.

Counsel for respondent: Chesley, Stanley M.

try	Date	Note	Proceedings and Orders
1	Oct 11 1985	G	Petition for writ of certiorari filed.
2	Nov 12 1985		Brief of respondents Larry J. Thompson, et al. in opposition filed.
3	Nov 13 1985		DISTRIBUTED. November 27, 1985
4	Nov 21 1985	X	Reply brief of petitioner Merrell Dow Pharm. filed.
5	Dec 2 1985		Petition GRANTED. *****
6	Jan 16 1986		Joint appendix filed.
7	Jan 16 1986		Brief of petitioner Merrell Dow Pharmaceuticals filed.
8	Feb 12 1986		Record filed.
9	Feb 15 1986		Brief of respondents Larry J. Thompson, et al. filed.
0	Mar 14 1986		SET FOR ARGUMENT, Monday, April 28, 1986. (2nd case)
1	Mar 14 1986		CIRCULATED.
2	Apr 8 1986		Record filed.
3	Apr 17 1986	X	Reply brief of petitioner Merrell Dow Pharm. filed.
4	Apr 28 1986		ARGUED.

85-619

, No. 85-\_\_\_\_\_

FILED

OCT 11 1985

JOSEPH F. SPANIOL, JR.  
CLERK

IN THE  
**SUPREME COURT OF THE UNITED STATES**

OCTOBER TERM, 1985

MERRELL DOW PHARMACEUTICALS INC.,  
Petitioner,

vs.

LARRY JAMES CHRISTOPHER THOMPSON AND  
DONNA LYNN THOMPSON AS NEXT FRIENDS AND  
GUARDIANS OF JESSICA ELIZABETH THOMPSON,  
LARRY JAMES CHRISTOPHER THOMPSON,  
INDIVIDUALLY AND DONNA LYNN THOMPSON,  
INDIVIDUALLY, *et al.*,  
Respondents.

Petition For a Writ of Certiorari to the  
United States Court of Appeals for the  
Sixth Circuit

Frank C. Woodside III  
2100 Fountain Square Plaza  
511 Walnut Street  
Cincinnati, Ohio 45202  
(513) 977-8200  
Counsel for Petitioner

Of Counsel:

John E. Schlosser  
Christine L. McBroom  
Kerry C. Green  
DINSMORE & SHOHL  
2100 Fountain Square Plaza  
511 Walnut Street  
Cincinnati, Ohio 45202

63/28

## QUESTIONS PRESENTED

1. Where a plaintiff alleges that a violation of a specific federal regulatory statute constitutes a rebuttable presumption of negligence and that such violation directly and proximately caused injury to plaintiff, does such claim, "necessarily depend" on resolution of an issue of federal law, so as to vest subject matter jurisdiction in the district court?

2. Where a claim which "necessarily depends" on resolution of an issue of federal law is joined with other claims of purely local law which would, if plaintiff prevails, obviate the federal question, does the pendency of such purely local claims deprive the district court of jurisdiction?<sup>1</sup>

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<sup>1</sup> The caption of the case in this Court does not reflect that there are two cases involved in this matter. The cases were decided together by the district court and were consolidated by the court of appeals. The names of the respondents in the second case are Neil Frazer MacTavish and Margaret MacTavish as Next Friends and guardians of Neil MacTavish, Neil Frazer MacTavish, individually, and Margaret MacTavish, individually.

Petitioner is a subsidiary of The Dow Chemical Company. The following subsidiaries and affiliates of The Dow Chemical Company have outstanding securities in the hands of the public: Dow Banking Corporation; Dow Chemical Iberica S.A.; Gruppo Lepetit S.p.A.; Ivon Watkins-Dow Limited; Laboratorios Industriales Farmaceuticos Ecuatorianos; Merrell Toraude et Compagnie; Oronzio De Nora Impianti Elettrochimici S.A.; and Pacific Chemicals Berhad.

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IN THE  
**SUPREME COURT OF THE UNITED STATES**

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OCTOBER TERM, 1985

No. 85-

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MERRELL DOW PHARMACEUTICALS INC.,  
Petitioner,

vs.

LARRY JAMES CHRISTOPHER THOMPSON AND  
DONNA LYNN THOMPSON AS NEXT FRIENDS AND  
GUARDIANS OF JESSICA ELIZABETH THOMPSON,  
LARRY JAMES CHRISTOPHER THOMPSON,  
INDIVIDUALLY AND DONNA LYNN THOMPSON,  
INDIVIDUALLY,  
Respondents.

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Petition For a Writ of Certiorari to the  
United States Court of Appeals for the  
Sixth Circuit

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Petitioner, Merrell Dow Pharmaceuticals Inc., defendant below, prays that a writ of certiorari issue to review the decision and order of the United States Court of Appeals for the Sixth Circuit reversing and remanding two cases to the United States District Court for the Southern District of Ohio with instructions to remand them to the state court from which they were removed.

**OPINIONS BELOW**

The opinion of the court of appeals is reported at 766 F.2d 1005 (6th Cir. 1985), and is printed in the Appendix at 1a. The opinion of the district court is unreported, and is printed in the Appendix at 4a.

## JURISDICTION

The judgment of the United States Court of Appeals for the Sixth Circuit was entered and filed on July 15, 1985. (App. at 8a). The 90th day after such judgment was Sunday, October 13, 1985. This petition was filed on or before Monday, October 14, 1985. The jurisdiction of this Court is invoked under 28 U.S.C. §§ 1254(1) and 2101(c).

## STATUTORY PROVISIONS INVOLVED

This case involves allegations of violations of certain sections of the Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1040, as amended (21 U.S.C. § 301, *et seq.*) the pertinent provisions of which are set forth in the Appendix at 10a.

## STATEMENT OF THE CASE

This petition concerns the subject matter jurisdiction of a United States district court in two cases in which respondents' right to relief necessarily depends upon resolution of a substantial question of federal law. The appellate decision at issue has already been cited by the district court as a basis to nullify a jury verdict for petitioner in over two hundred additional lawsuits in which petitioner had prevailed in a protracted trial of common issues. (App. at 31a). Such verdict, if undisturbed, would result in defense judgments.

Respondents are parents and children who allege in their complaints that the ingestion during pregnancy of the pharmaceutical product Bendectin caused the children's birth defects.<sup>2</sup> Bendectin is a prescription drug which was marketed for the treatment of nausea and vomiting of pregnancy. Respondents are citizens and residents of the United Kingdom (Scotland) and Ontario, Canada. (App. at 13a, 22a) Petitioner is a pharmaceutical manufacturer incorporated in Delaware with its principal place of business in Hamilton County, Ohio. (App. at 13a, 23a). Respondents originally filed their actions in the Court of Common Pleas of Hamilton County, Ohio. (App. at 12a, 22a).

<sup>2</sup> Respondents' complaints are printed in the Appendix at 12a and 22a.

Respondents sued petitioner for violating the Federal Food, Drug and Cosmetic Act in regard to its product, Bendectin, which is manufactured, marketed and regulated in the United States. Any products ingested by respondents would not, however, have been petitioner's product. In their motion to remand, respondents alleged the product ingested to be Debendox, the tradename for the United Kingdom version of Bendectin.<sup>3</sup> (In fact, the Thompson respondents would have ingested the Canadian-made version of Bendectin.) Respondents did not sue the foreign manufacturers or sellers of those products, nor did they allege violations of the regulatory laws of those countries. (App. at 12a, 22a).

Numerous other foreign citizens had filed similar suits against petitioner prior to the time respondents filed the instant actions. All but one of the earlier actions had been dismissed by the District Court for the Southern District of Ohio, upon petitioner's motions, on grounds of *forum non conveniens*. Twelve of those dismissals, including actions by other Scottish citizens, had been upheld by the United States Court of Appeals for the Sixth Circuit. Several, including an action filed by citizens of Ontario, Canada, were on appeal at the time the instant actions were filed.

Subsequent to the precedent set by these dismissals and affirmances, respondents filed suit in the Court of Common Pleas of Hamilton County, Ohio. In their first "cause of action," respondents allege that petitioner was negligent in developing, marketing, producing, manufacturing, distributing, and selling the drug Bendectin. This cause of action makes no reference to the federal law. (App. at 13a, 24a). Respondents' fourth cause of action asserts that petitioner violated sub-section (n) of section 201 and subsections (a), (f)(2) and (j) of section 502 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321(n), 352(a)(f)(2) and (j), by "misbranding" Bendectin, and that these violations "consti-

<sup>3</sup> In accordance with Rule 19.1 of the Rules of the Supreme Court of the United States, the record below, which contains the motion to remand filed by respondents, has not yet been certified to this Court.

tute a rebuttable presumption of negligence." (App. at 16a, 26a). Respondents allege that "... defendant's violation of said federal statutes directly and proximately caused the injuries suffered . . ." by them (App. at 18a, 27a).

Pursuant to 28 U.S.C. § 1441(b), and based on the fourth cause of action, petitioner removed both cases to the United States District Court for the Southern District of Ohio. Respondents moved the district court to remand the cases to the state court, claiming that the fourth causes of action did not confer federal question jurisdiction because they were based on state law. The district court found, however, that, in accordance with this Court's definitions of "arising under" jurisdiction set forth in *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921), and *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983), federal question jurisdiction did exist over the cases and that they were properly removed. (App. at 6a). Relying on its previous dismissals of actions brought by citizens and residents of foreign countries and the affirmances thereof, the district court then dismissed the actions, upon petitioner's motion, on grounds of *forum non conveniens*. (App. at 7a-8a).

Respondents appealed. The court of appeals reversed and remanded the cases to the district court with instructions to remand them to the state court. The court of appeals stated:

Plaintiffs' causes of action referred to the FDCA [Food, Drug and Cosmetic Act] merely as one available criterion for determining whether Merrell Dow was negligent. Because the jury could find negligence on the part of Merrell Dow without finding a violation of the FDCA, the plaintiffs' causes of action did not necessarily depend upon a question of federal law. Consequently, the causes of action did not arise under federal law and, therefore, were improperly removed to federal court.

(App. at 3a). Thus, the appellate court ruled that, since respondents' non-federal negligence claim did not necessarily depend upon resolution of the federal question, no federal

jurisdiction could exist. It overruled the district court's conclusion that, since respondents' fourth causes of action would necessarily depend upon resolution of federal questions, the court had subject matter jurisdiction.

Based on this appellate decision, the district court also dismissed or remanded, for want of jurisdiction, over two hundred additional cases which had already been tried to verdict.<sup>4</sup> (App. at 31a). These cases were filed in Ohio courts upon complaints nearly identical to those filed by respondents. Some of these cases were removed by petitioner to federal court. Others were filed by plaintiffs in federal court alleging federal jurisdiction. Petitioner had prevailed in a consolidated "common issues" trial involving these cases and approximately nine hundred more. The jury concluded that Bendectin does not cause birth defects. Those cases were still pending before the district court on plaintiffs' motion for new trial, which has since been denied. The court of appeals' decision herein has thus affected not only the cases at bar, but has caused the revival of over two hundred additional actions against petitioner.

## REASONS FOR GRANTING THE WRIT

This case presents an important question of the subject matter jurisdiction of a district court over suits in which one cause of action alleges violations of federal law and another cause of action, based on the same legal theory, alleges a purely state law claim. The court of appeals' decision on these questions conflicts with this Court's decision in *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983). This Court should grant certiorari to clarify that: 1) a cause of action may "arise under" a federal law where the right to relief claimed in that cause of action necessarily

<sup>4</sup> The cases at bar are a part of this remand order. The order of remand has been stayed upon petitioner's motion requesting amendment of other aspects of the order.

depends on a substantial question of federal law; and 2) the joining of a purely local cause of action with a cause of action arising under federal law, though both request the same relief, does not destroy federal question jurisdiction.

**I. WHERE A PLAINTIFF ALLEGES THAT A VIOLATION OF A SPECIFIC FEDERAL REGULATORY STATUTE CONSTITUTES A REBUTTABLE PRESUMPTION OF NEGLIGENCE AND THAT SUCH VIOLATION HAS DIRECTLY AND PROXIMATELY CAUSED PLAINTIFFS' INJURIES, SUCH CLAIM "NECESSARILY DEPENDS" ON RESOLUTION OF AN ISSUE OF FEDERAL LAW, SO AS TO VEST SUBJECT MATTER JURISDICTION IN THE DISTRICT COURT.**

**A. THE DECISION BELOW CONFLICTS WITH A RECENT DECISION OF THIS COURT IN THAT IT DENIES SUBJECT MATTER JURISDICTION OVER A CLAIM NECESSARILY DEPENDENT ON RESOLUTION OF A SUBSTANTIAL FEDERAL ISSUE.**

This Court's decision in *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983), is the most recent statement of the scope of subject matter jurisdiction over claims "arising under" federal law. The *Franchise* decision states:

Congress has given the lower federal courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a well-pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law.

*Id.* at 28 (emphasis added).

In the cases at bar, it was uncontested that the Federal Food, Drug and Cosmetic Act does not provide a private right of action for its violation.<sup>5</sup> Thus, federal law does not "create" the cause of action. Respondents' right to relief for petitioner's alleged violations of the Act does, however, "necessarily depend" on resolution of a substantial question of federal law. This the appellate court neither disputed nor acknowledged. It concerned itself solely with whether the common law negligence claim was also dependent for its outcome on the federal question.

In *Franchise*, this Court restated one of the bases for jurisdiction over claims "arising under" federal law: "We have often held that a case 'arose under' federal law where the vindication of a right under state law necessarily turned on some construction of federal law, see, e.g., *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921); *Hopkins v. Walker*, 244 U.S. 486 (1917)." *Id.* at 9.

Based on the law set forth in *Franchise*, petitioner removed the cases at bar from state court because the fourth cause of action in each arose under federal law: The vindication of respondents' right under state law would necessarily turn on a construction of federal law. As the district court held: "Although plaintiffs' fourth cause of action is technically a claim for negligence pursuant to state law, the sole basis for the claim is the alleged violation of the federal Act by defendant." (App. at 7a-8a).

In *Franchise*, this Court held: "[F]ederal jurisdiction is unavailable unless it appears that some substantial, disputed question of federal law is a necessary element of one of the

<sup>5</sup> It is also uncontested that the fourth cause of action alleges a private right of action for violation of the Federal Food, Drug and Cosmetic Act. Neither party had moved for a dismissal of that allegation or for a complaint amendment to delete it prior to the dismissal of this case by the district court on *forum non conveniens* grounds. Thus, while the parties may now agree that there is no private right of action, the allegation alone in the complaint supplied a sufficient basis for federal jurisdiction.

well-pleaded state claims, or that one or the other claim is 'really' one of federal law." *Id.* at 13 (emphasis added). The appellate court below read this pronouncement as if it required more than one state claim to be dependent on the federal question. It failed to recognize that, without first construing and applying the federal statute, there is no right to relief available to respondents under their fourth cause of action. Federal law is a necessary element, indeed *the* essential ingredient, of *one* of respondents' state claims.

The use of the term "negligence" to categorize the first and fourth causes of action was an oversimplification by the court of appeals. The two claims were quite distinct. Common law negligence is a breach of a duty of care owed by petitioner to respondents which allegedly proximately caused their injuries. This was the first cause of action. The fourth cause of action dispenses with the need to prove the standard of care and breach of that standard. It substitutes a violation of federal law for these two elements. For the fourth cause of action, it is not only upon the acts of petitioner, but also upon their character as *unlawful as a federal matter*, that respondents founded their claim.

Under the first cause of action, respondents must prove breach of due care. Under the fourth, petitioner has the duty to go forward with proof of its due care or suffer the adverse effect of the presumption. The only point in common between the first and fourth causes of action is the necessity of proving proximately caused injury, a necessity in *every* tort claim. The easy label of "negligence" overlooks their predominating differences.

The Federal Food, Drug and Cosmetic Act is a comprehensive statute which elaborately regulates the manufacture and marketing of pharmaceutical products. While the parties now agree that it does not provide a private right of action for its alleged violation, respondents nonetheless asserted a cause of action for its violation by alleging a state law "effect" for its violation. It is clear that it is the federal violation upon which that claim is based and depends. As stated in *Franchise*:

[F]or purposes of § 1331 an action "arises under" federal law "if in order for the plaintiff to secure the relief sought he will be obliged to establish both the correctness and the applicability to his case of a proposition of federal law."

*Id.* at 9 (citations omitted). This definition was read by the appellate court below in the narrowest fashion. The district court had ruled that, in order for the respondents to secure the relief they sought *in the fourth cause of action*, they would be obliged to establish both the applicability to their cases of the Federal Food, Drug and Cosmetic Act and the violations which they asserted. The court of appeals did not disagree, but found the essential federal element of the fourth cause of action inadequate to vest jurisdiction because of respondents' state law negligence claim.

The conclusion which the district court held decisive of jurisdiction, i.e., that the alleged Food, Drug and Cosmetic Act violations were an essential element of respondents' fourth cause of action, was an issue which the court of appeals found no necessity to reach. Had the court of appeals analyzed each of respondents' causes of action separately as *Franchise* requires, it would necessarily have found that the fourth cause of action conferred jurisdiction.

The effect of the court of appeals' decision is to leave to the state court the necessity to make a detailed analysis and application of the statute allegedly violated. This would include the unusual allegations made by respondents herein that the statutory and regulatory requirements of the United States Food, Drug and Cosmetic Act should be "exported" to govern the activities of foreign pharmaceutical companies in other nations, the United Kingdom and Canada in this instance. Respondents' allegations also raise the issue of the interaction of United States law and parallel foreign regulatory schemes. No federal court has yet confronted the issue of extra-territorial application of the Food, Drug and Cosmetic Act. This question should not first be addressed, without guidance, by a state court.

**II. WHERE A CLAIM WHICH "NECESSARILY DEPENDS" ON RESOLUTION OF AN ISSUE OF FEDERAL LAW IS JOINED WITH OTHER CLAIMS OF PURELY LOCAL LAW WHICH WOULD, IF PLAINTIFF PREVAILS, OBVIATE THE FEDERAL QUESTION, THE PENDENCY OF SUCH LOCAL CLAIMS DOES NOT DEPRIVE THE DISTRICT COURT OF JURISDICTION.**

**A. THE DECISION OF THE COURT OF APPEALS WOULD SIGNIFICANTLY CURTAIL FEDERAL SUBJECT MATTER JURISDICTION IN CASES INVOLVING PARALLEL, PENDENT LOCAL CLAIMS.**

In *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983), this Court held that federal question jurisdiction exists when a "plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law." *Id.* at 27-28. The Court's reference to "the cause of action" and "right to relief" in the singular *did not*, however, imply that a lawsuit would necessarily have *only one* cause of action and *only one* right to relief asserted. As the Court further stated:

Appellant's complaint sets forth two 'causes of action,' one of which expressly refers to ERISA: if *either* comes within the original jurisdiction of the federal courts, removal was proper as to the whole case . . . . [O]riginal federal jurisdiction is unavailable unless it appears that some substantial, disputed question of federal law is a necessary element of *one* of the well-pleaded state claims or that *one or the other* claim is 'really' one of federal law. . . .

*Id.* (emphasis added).

The court of appeals, however, misread these pronouncements. It looked beyond the cause of action which raised the federal question and examined the *entire complaint* to see whether respondents might prevail on the state law negligence claim without resolving the federal question. Jurisdiction was held lacking because a different and separately pleaded cause of action (but one without reference to federal law) gave respondents a potential "right to relief" that did not "necessarily depend" on the resolution of the federal question. Thus, a new rule of law was articulated: If a plaintiff *might* prevail on a state law claim without relying on a claim involving an essential federal question, there is no federal jurisdiction and removal is improper.

In the cases at bar, the complaints each contain a first and fourth cause of action which are separate and distinct. The first cause of action alleges common law negligence and makes no reference to federal law. The fourth cause of action asserts and relies upon violations of a federal statute and a substantive presumption resulting therefrom. The first and fourth causes of action are not interchangeable.

The court of appeals' decision overlooks this Court's instruction in *Franchise* that *each* claim be considered separately in determining whether there is a federal question. A court may not merge causes of action to make this determination. Subject matter jurisdiction is available so long as a "question of federal law is a necessary element of *one* of the well-pleaded state claims. . . ." *Id.* at 13 (emphasis added). The decision below compels the unwarranted denial of subject matter jurisdiction whenever a complaint includes an additional, state-law-based claim not involving a federal question. This opinion impairs both the "consistent application" of the federal jurisdictional statutes that this Court emphasized in *Franchise*, and the objective of the uniform application of the removal statute noted in *Shamrock Oil and Gas Corp. v. Sheetes*, 313 U.S. 100, 104 (1940).

The court of appeals further erred in giving an overbroad reading to "right to relief." The court reasoned that, if the

respondents might prevail on a claim other than the one presenting the federal question, then their "right to relief," in this broadest sense, could not "necessarily depend" on the resolution of the federal question. Viewing the complaint as it did, as including a single claim of negligence and requesting a single right to relief, the court of appeals saw the federal statutory violations as but one means for potentially granting that single right to relief. This rule of law erroneously extends the *Franchise* decision to curtail federal jurisdiction over claims which are necessarily dependent on substantial federal questions.

**B. THE COURT OF APPEALS ERRONEOUSLY DISTINGUISHED BETWEEN FEDERALLY CREATED CLAIMS AND CLAIMS NECESSARILY DEPENDENT ON A FEDERAL QUESTION, RULING THAT THE LATTER TYPE OF FEDERAL QUESTION JURISDICTION COULD NOT SURVIVE THE PENDENCY OF LOCAL CLAIMS WHICH SEEK THE SAME RELIEF.**

Traditional concepts of subject matter jurisdiction of the federal courts recognize that federal questions often arise in lawsuits which also present claims of a purely local character. So long as these claims arise out of the same nucleus of facts, such that they comprise a single "case" which a plaintiff would normally try in one suit, the federal court has jurisdiction to decide them *all*. *United Mine Workers v. Gibbs*, 383 U.S. 715, 725 (1966).

The fact that a non-federal claim might be dispositive and theoretically moot the federal question has not been held to destroy jurisdiction. For example, where the federal question is of a constitutional character, the objective of the court is to avoid decision of the federal question if possible, and to dispose of the whole case on state law grounds. *Siler v. Louisville & Nashville R.R. Co.*, 213 U.S. 175, 193 (1909).

"Pendent jurisdiction . . . exists whenever there is a claim 'arising under . . . the Laws of the United States,' . . . and the relationship between that claim and the state claim permits the conclusion that the entire action before the court comprises but one constitutional 'case.'" *United Mine Workers v. Gibbs*, 383 U.S. 715, 725 (1966). This pronouncement makes no distinction between federally created claims and claims necessarily dependent on resolution of federal questions. Both "arise under" federal law and both can support pendent state claims. Under the decision of the court of appeals, however, pendent jurisdiction would only be available when the complaint states a federally *created* claim. In the case of a claim "necessarily dependent" on an issue of federal law, the pendency of a purely local claim destroys the federal jurisdiction, otherwise available, if the local claim might be dispositive.

Such a result undercuts the very reasoning that prompted Chief Justice Marshall to validate pendent jurisdiction in *Osborn v. Bank of United States*, 22 U.S. (9 Wheat.) 738 (1824).

We think, then, that when a question to which the judicial power of the Union is extended by the constitution, forms an ingredient of the original cause, it is in the power of Congress to give the Circuit Courts jurisdiction of that cause, although other questions of fact or of law may be involved in it.

*Id.* at 823. As Justice Rehnquist has more recently noted, "A different result [in *Osborn*] would have forced substantial federal cases into state courts for adjudication simply because they involved non-federal issues as well as federal ones." *Hagans v. Lavine*, 415 U.S. 528, 554 (1973) (Rehnquist, J., dissenting). The decision of the court of appeals is precisely that "different result."

Once federal question jurisdiction is established as to one claim, purely local causes of action do not destroy jurisdiction, but rather themselves become subject to it. In *Siler v.*

*Louisville & Nashville Railroad Co.*, 213 U.S. 175 (1909), this Court found federal jurisdiction even though the relief actually afforded plaintiff was based solely on the invalidation of a state regulation *on state law grounds*, leaving the federal constitutional questions unresolved. The Court stated:

The Federal questions as to the invalidity of the state statute because, as alleged, it was in violation of the Federal Constitution, gave the circuit court jurisdiction, and, having properly obtained it, that court had the right to decide all the questions in the case, even though it decided the Federal questions adversely to the party raising them, *or even if it omitted to decide them at all, but decided the case on local or state questions only.*

*Id.* at 191 (emphasis added). *Siler* clearly provides that federal question jurisdiction endures, through the concept of pendent jurisdiction, even when the plaintiffs' actual recovery is ultimately based *solely* on the state law cause of action.

In *Hurn v. Oursler*, 289 U.S. 238 (1932), this Court expanded the scope of pendent jurisdiction beyond federal questions arising under the Constitution to include federal questions arising under federal statutes and regulations. The Court again sanctioned the retention of federal jurisdiction over purely local causes of action which had been "orphaned" by the dismissal of the claim raising a federal question which had originally conferred that jurisdiction.

*United Mine Workers of America v. Gibbs*, 383 U.S. 715 (1966), reaffirmed the principle that federal jurisdiction is retained and pendent jurisdiction survives even though local causes of action are in themselves sufficient to afford the plaintiff a right to full relief. This Court upheld the jurisdiction of the lower federal court though it was "true that the [federal] claims ultimately failed and that the only recovery allowed was on the state claim." *Id.* at 728.

The decision of the appellate court below is fatally flawed by neglecting these rules of law. Federal question jurisdiction, once established, is not erased by the inclusion of a state-

created cause of action upon which the plaintiffs' entire recovery might be based.

The appellate opinion below allows a plaintiff relying on a necessary federal element to his claim, through artful pleading, to avoid federal jurisdiction merely by pleading an additional cause of action seeking the same relief but without reference to federal law. Federal jurisdiction will be side-stepped and substantial federal claims will be forced into state court merely because they involve non-federal issues incorporated by the plaintiff to avoid federal jurisdiction. *See, Hagans v. Lavine*, 415 U.S. 528, 554 (1973) (Rehnquist, J., dissenting). The precedent set by the appellate court below will allow a plaintiff to manipulate the pleadings such that a right to relief truly dependent on the resolution of federal law can be anchored to state court by a second cause of action seeking the same relief. Such manipulation cannot control the jurisdiction of the federal courts.

## CONCLUSION

The appellate court's opinion below conflicts with this Court's latest decision in *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983), and effectively eliminates the exercise of federal question jurisdiction when a claim arising under federal law is joined with a claim based on state law seeking the same relief. The importance of this jurisdictional question and its far-reaching implications cannot be overlooked. For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

Frank C. Woodside III  
2100 Fountain Square Plaza  
511 Walnut Street  
Cincinnati, Ohio 45202  
Counsel for Petitioner

Of Counsel:

John E. Schlosser  
Christine L. McBroom  
Kerry C. Green  
DINSMORE & SHOHL  
2100 Fountain Square Plaza  
511 Walnut Street  
Cincinnati, Ohio 45202

No. 84-3418

UNITED STATES COURT OF APPEALS  
FOR THE SIXTH CIRCUIT

LARRY JAMES CHRISTOPHER THOMPSON, et al.,

*Plaintiffs-Appellants,*

v.

MERRELL DOW PHARMACEUTICALS, INC.,

*Defendant-Appellee.*

ON APPEAL from the  
United States District  
Court for the South-  
ern District of Ohio.

Decided and Filed July 15, 1985

Before: JONES and KRUPANSKY, Circuit Judges; and HULL, Chief District Judge.\*

JONES, Circuit Judge. This appeal presents the issue of whether actions filed in state court are properly removable to federal court if the complaints allege in part that the defendant violated the Food, Drug and Cosmetic Act and that this violation constituted "a rebuttable presumption of negligence." Plaintiffs-appellants contend that these cases presented no federal question upon which removal could be properly based. We agree and reverse and remand.

Plaintiffs-appellants, the Thompsons and the MacTavishes, are residents of Scotland and Canada respectively. They filed their complaints against defendant-appellee, Merrell Dow Pharmaceuticals, Inc., in the Court of Common Pleas, Hamilton County, Ohio. The complaints alleged that Mrs.

\* Honorable Thomas G. Hull, District Judge, United States District Court for the Eastern District of Tennessee, sitting by designation.

Thompson and Mrs. MacTavish ingested Benedectin, a drug developed, produced, manufactured, and sold by Merrell Dow, and that the ingestion of the drug resulted in the birth defects suffered by both Jessica Thompson and Neil MacTavish. Each complaint alleged liability based upon the state-created theories of common law fraud, negligence, strict liability, and breach of warranty. They also alleged that Merrell Dow violated certain provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-392 (FDCA) and that those violations establish a rebuttable presumption of negligence. Pursuant to 28 U.S.C. § 1441, Merrell Dow removed these actions to the district court where they were consolidated. Plaintiffs filed a motion to remand under § 1447(c) for lack of subject matter jurisdiction. The district court denied plaintiffs' motion to remand and granted Merrell Dow's motion to dismiss on the ground of forum non conveniens. Appellants then filed this appeal.

Removal jurisdiction in a federal district court is premised upon 28 U.S.C. § 1441. Section 1441(a) provides for removal of actions generally, and § 1441(b) limits a defendant's ability to remove actions from a state court to situations where the defendant is not a citizen of the state in which such action is brought. Section 1441(c) permits a district court to determine all issues raised in an action when one claim, which would be removable if sued upon alone, is joined with one or more otherwise non-removable claims. The standard for determining when an action is removable is whether the court would have had jurisdiction, subject to the limitations of § 1441(b), if the action had been instituted originally in federal court under 28 U.S.A. § 1331 or § 1332. See *Franchise Tax Board v. Construction Laborers Vacation Trust*, 103 S. Ct. 2841, 2845 (1983). Consequently, a case removed to federal court under the guise of federal question jurisdiction presents a federal question when it "arises under" federal law. In *Franchise Tax Board*, the Court stated:

Under our interpretations, Congress has given the lower courts jurisdiction to hear, originally or by removal from

a state court, only those cases in which a well pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law.

*Id.* at 2856.

The parties agree that the FDCA does not create or imply a private right of action for individuals injured as a result of violations of the Act. Federal question jurisdiction would, thus, exist only if plaintiffs' right to relief *depended necessarily* on a substantial question of federal law. Plaintiffs' causes of action referred to the FDCA merely as one available criterion for determining whether Merrell Dow was negligent. Because the jury could find negligence on the part of Merrell Dow without finding a violation of the FDCA, the plaintiffs' causes of action did not depend necessarily upon a question of federal law. Consequently, the causes of action did not arise under federal law and, therefore, were improperly removed to federal court. See *Zeig v. Shearson/American Express, Inc.*, 592 F. Supp. 612, 613-14 (E.D. Va. 1984); *State of Florida ex rel. Broward County*, 329 F. Supp. 364, 366 n.3 (S.D. Fla. 1971).

Accordingly, the judgment of the district court is REVERSED and the case is REMANDED with instructions to remand the cases to the Court of Common Pleas for Hamilton County, Ohio, where they were first filed.

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

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MDL #486

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IN RE: RICHARDSON-MERRELL, INC.  
"BENEDICTIN" PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATED TO:

THOMPSON	C-1-83-1436
MacTAVISH	C-1-83-1437

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ORDER DENYING PLAINTIFFS'  
MOTION TO REMAND (Doc. No. 979)  
AND GRANTING DEFENDANT'S  
MOTIONS TO DISMISS ON  
*FORUM NON CONVENIENS* GROUNDS  
(Doc. Nos. 1132, Thompson; 1133, MacTavish)  
[Filed May 14, 1984]

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This matter is before the Court on plaintiffs' Motion (Doc. No. 979) to remand the above-captioned cases to the Court of Common Pleas, Hamilton County, Ohio, and on defendant's Motions (Doc. Nos. 1132 and 1133) to dismiss on *forum non conveniens* grounds. For the reasons which follow, plaintiffs' Motion will be denied and defendant's Motions will be granted.

I. Motion to Remand

These cases were originally filed in the Court of Common Pleas, Hamilton County, Ohio, and removed by defendants to this Court pursuant to 28 U.S.C. § 1441. Removal was premised on this Court's jurisdiction over cases "arising under the Constitution, treaties or laws of the United States." See 28 U.S.C. § 1441(b). See also 28 U.S.C. §§ 1441(a), 1331.<sup>1</sup> Plaintiffs subsequently filed their Motion to Remand, asserting that federal-question jurisdiction was lacking and that the case had been improvidently removed from state court.<sup>2</sup>

Specifically at issue is the fourth cause of action in each Complaint. That cause of action, used by defendant as the basis for removal, alleges negligence resulting from defendant's alleged failure to comply with the labeling provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("the Act"). After outlining pertinent provisions of the Act in Paragraphs 18 through 24 of each Complaint, plaintiffs set forth the following in Paragraphs 25 through 27:

25. That the promotion of said drug, Benedectin, by the defendant . . . constituted misbranding of said pharmaceutical drug per sub-sections (a), (f)(2) and (j) of § 502 and (u) of § 201 of [the Act].

26. That violation of said Federal Statutes in the promotion of said drug, Bendectin, by the Defendant herein enumerated, constitutes a rebuttable presumption of negligence.

27. That the Defendant's violation of said Federal Statutes directly and proximately caused the injuries suffered by [plaintiffs] . . .

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<sup>1</sup> Section 1441(c) provides for the removal of an entire of an entire case if it contains at least one "separate and independent claim or cause of action, which would be removable if sued upon alone." The district court may, in its discretion, determine all the issues in the case or remand those not within its original jurisdiction.

<sup>2</sup> The parties agree that federal-question jurisdiction provides the only arguable basis for removal of these cases.

The question facing the Court is whether plaintiffs' fourth cause of action states a claim "arising under" the laws of the United States.

In attempting to clarify the phrase "arising under," the Supreme Court has formulated definitions employing varying language. See, e.g., *Gully v. First National Bank*, 299 U.S. 109 (1936); *Moore v. Chesapeake & Ohio Ry.*, 291 U.S. 205 (1934); *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921); *American Well Works Co. v. Layne & Bowler Co.*, 241 U.S. 257 (1916).

Upon examination of the pertinent cases, this Court concludes that the definition set forth in *Smith, supra*, provides the appropriate standard for analysis. Cf., *T.B. Harms Co. v. Eliscu*, 339 F.2d 823, 827 (2nd Cir. 1964), *cert. denied*, 381 U.S. 915 (1965) (*Smith* was "path-breaking" opinion). See also *Franchise Tax Bd. v. Construction Laborers Vacation Trust*, \_\_\_\_ U.S. \_\_\_\_, 103 S.Ct. 2841, 2846 (1983).

In *Smith*, the Supreme Court stated the "general rule" as follows:

[W]here it appears from the bill or statement of the plaintiff that the right to relief depends upon the construction or application of the Constitution or laws of the United States, and that such federal claim is not merely colorable, and rests upon a reasonable foundation, the District Court has jurisdiction. . . .

*Smith, supra*, at 199.<sup>3</sup>

Applying the rule as stated in *Smith*, the Court concludes that federal-question jurisdiction exists over these cases and that they were properly removed. Although plaintiffs' fourth cause of action is technically a claim for negligence purusant

<sup>3</sup> This Court recognizes that *Smith* is in apparent conflict with *Moore, supra*, and that the conflict appears, at first blush, to be irreconcilable. See, M. Redish, *Federal Jurisdiction*, 67 (1980). However, subsequent federal court decisions have reconciled and distinguished the two cases on the basis of the state statutory schemes involved in each. See *Abrams v. Citibank*, 537 F.Supp. 1192, 1196 (S.D. N.Y. 1982). The case at bar is analogous to *Smith* and therefore distinguishable from *Moore*.

to state law, the sole basis for the claim is the alleged violation of the federal Act by defendant. Therefore, the key issue with respect to that cause of action is whether defendant's conduct violated the Act. Phrased in terms of the *Smith* standard, plaintiffs' "right to relief depends upon the . . . application of the . . . laws of the United States." *Smith, supra*, at 199. Accordingly, the Court holds that plaintiffs' fourth cause of action arises under the laws of the United States and that these cases were properly removed to federal court.<sup>4</sup> Plaintiff's Motion to Remand will be denied.

## II. Motions to Dismiss

The precise issues raised by defendant's Motions to Dismiss on *forum non conveniens* grounds have previously been considered by the Court under factual circumstances virtually identical with those at bar. See *order Granting Defendant's Motion to Dismiss in Vandervliet* (Doc. No. 1578) (facts virtually identical to *Thompson*); *In Re Richardson-Merrell, Inc.*, 545 F.Supp. 1130 (S.D. Ohio 1983), *aff'd. sub nom Dowling v. Richardson-Merrell, Inc.*, 727 F.2d 608 (6th Cir. 1984) (facts identical to *MacTavish*). Defendant's Motion with respect to *Thompson* will be granted for the reasons set forth in *Vandervliet, supra*, and defendant's Motion with respect to *MacTavish* will be granted for the reasons set forth in *In Re Richardson-Merrell, Inc., supra*. The granting of each of defendant's motions is subject to the five conditions set forth in *Dowling, supra*, at 611, 616.

Accordingly, for the reasons set forth above, and subject to the conditions noted, plaintiffs' Motion to Remand (Doc. No. 979) is hereby DENIED and defendant's Motions to Dismiss on

<sup>4</sup> In asserting a lack of federal-question jurisdiction, plaintiffs argue, *inter alia*, that jurisdiction is lacking because no private right of action exists under the Act. The Court is not impressed by this argument. This is not a situation where plaintiffs are seeking some form of relief under the Act itself.

8a

*forum non conveniens* grounds (Doc. Nos. 1132 and 1133) are hereby GRANTED.

IT IS SO ORDERED.

/s/ CARL B. RUBIN, Chief Judge  
United States District Court

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UNITED STATE COURT OF APPEALS  
FOR THE SIXTH CIRCUIT

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No. 84-3418

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LARRY JAMES CHRISTOPHER THOMPSON, et al.,  
Plaintiffs-Appellants,

v.

MERRELL DOW PHARMACEUTICALS, INC., f/k/a  
Richardson Merrell, Inc.,  
Defendant-Appellee.

---

Before: JONES and KRUPANSKY, Circuit Judges; and  
HULL, Chief District Judge.

**JUDGMENT**

[Filed July 15, 1985]

ON APPEAL from the United States District Court for the  
Southern District of Ohio.

THIS CAUSE came on to be heard on the record from the  
said District Court and was argued by counsel.

9a

ON CONSIDERATION WHEREOF, It is now here  
ordered and adjudged by this court that the judgment of the  
said District Court in this case be and the same is hereby  
reversed and the case is remanded with instructions consistent  
with this opinion.

It is further ordered that Plaintiffs-Appellants recover from  
Defendant-Appellee the costs on appeal, as itemized below,  
and that execution therefor issue out of said District Court, if  
necessary.

ENTERED BY ORDER OF THE  
COURT

John P. Hehman, Clerk

/s/ JOHN P. HEHMAN,  
Clerk

ISSUED AS AMENDED MANDATE: August 15, 1985  
(COSTS: Awarded to appellant)

Filing fee .....	\$ 70.00
Printing .....	\$332.50
Total .....	\$402.50

A True Copy.

Attest:

/s/ GARY McCARTHY  
Deputy Clerk

**Food, Drug and Cosmetic Act**

52 Stat. 1040 § 201(n)

[21 U.S.C. § 321(n)]

**§ 321. Definitions; generally**

For the purposes of this chapter—

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions or use as are customary or usual.

52 Stat 1040 § 502(a), (f)(2) and (j)

[21 U.S.C. § 352(a), (f)(2) and (j)]

**§ 352. Misbranded drugs and devices**

A drug or device shall be deemed to be misbranded—

**False or misleading label**

(a) If its labeling is false or misleading in any particular.

\* \* \*

**Directions for use and warnings on label**

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Pro-*

*vided*, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

\* \* \*

**Health-endangering when used as prescribed**

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

COURT OF COMMON PLEAS  
HAMILTON COUNTY, OHIO

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Case No. A8307058

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LARRY JAMES CHRISTOPHER THOMPSON and  
DONNA LYNN THOMPSON as Next Friends and  
Guardians of JESSICA ELIZABETH THOMPSON, A Minor  
222 Church Street  
Napanea, Ontario Canada K7R1C6

LARRY JAMES CHRISTOPHER THOMPSON, Individually  
222 Church Street  
Napanea, Ontario Canada K7R1C6

DONNA LYNN THOMPSON, Individually  
222 Church Street  
Napanea, Ontario Canada K7R1C6

Plaintiffs,

vs.

MERRELL-DOW PHARMACEUTICALS, INC.,  
(formerly known as Richardson-Merrell, Inc.)  
a Delaware Corporation  
2110 East Galbraith Road  
Cincinnati, Ohio 45215

Defendant.

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COMPLAINT AND JURY DEMAND

[Filed September 1, 1983]

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Now come the Plaintiffs, Larry James Christopher Thomp-

son and Donna Lynn Thompson as Next Friends and  
Guardians of Jessica Elizabeth Thompson, a Minor, and In-  
dividually, and state their causes of action as follows.

FIRST CAUSE OF ACTION

1. The Plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson, as Next Best Friends and Guardians of Jessica Elizabeth Thompson, a Minor and Individually, state that they are residents of the City of Ontario, Country of Canada, Providence of Napanea.

2. That Defendant Merrell-Dow Pharmaceutical, Inc., FDDB Merrell-National Laboratories, Division of Richardson-Merrell, Inc., is a Delaware corporation with its principal place of business in the City of Cincinnati, County of Hamilton, State of Ohio.

3. That on or about December of 1978, Plaintiff Donna Lynn Thompson became pregnant with Jessica Elizabeth Thompson.

4. That during the first trimester of said pregnancy, Donna Lynn Thompson began to experience nausea for which her obstetrician prescribed the drug product known as Bendectin.

5. That said product, Bendectin, is a prescription drug made and distributed by the Defendant.

6. That Jessica Elizabeth Thompson was born September 21, 1979 subsequent to which it became obvious that the minor suffered from multiple deformities, including but not limited to, recto-vulvar fistula, anal atresia and sacral agenesis.

7. That as a result of said abnormalities, Jessica Elizabeth Thompson was caused to undergo extensive medical treatment and was and will continue to be required to undergo further medical treatment.

8. That the injuries suffered by Jessica Elizabeth Thompson were directly and proximately caused by the administration of the drug product Bendectin to Donna Lynn Thompson during the first trimester of pregnancy.

9. That the negligence of the Defendant in developing, marketing, producing, manufacturing, distributing and selling a product that Defendant knew or should have known could cause injuries and defects in children such as Jessica Elizabeth Thompson upon ingestion during pregnancy, directly and proximately caused said injuries; that the injuries were directly and proximately caused by the negligence of the Defendant in failing to test or inadequately testing the potential birth defect producing effects upon ingestion of Bendectin during pregnancy; that injuries were caused, directly and proximately by the negligence of the Defendant in failing to warn the users of Bendectin of the potential birth defect producing effects upon ingestion during pregnancy.

10. That as a direct and proximate result of the aforementioned negligence of the Defendant, Jessica Elizabeth Thompson was and will be caused to suffer considerable pain and suffering and to undergo further medical treatment, and Plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson, as parents of Jessica Elizabeth Thompson, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Larry James Christopher Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff, Donna Lynn Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

### SECOND CAUSE OF ACTION

11. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 10 and for their Second Cause of Action state as follows.

12. That Defendant expressly and impliedly warranted that its product, Bendectin, was of merchantable quality and fit and safe for its intended purposes and uses.

13. That Defendant breached said express and implied warranties of merchantability, fitness and safety and that said breach directly and proximately caused the injuries suffered by Jessica Elizabeth Thompson, a Minor, and that as a direct and proximate breach of the aforementioned warranties, said Minor was and will be caused to suffer considerable pain and suffering, and to undergo continuous medical treatment, and Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as parents of Jessica Elizabeth Thompson were and will be caused to suffer considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff, Larry James Christopher Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff, Donna Lynn Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

### THIRD CAUSE OF ACTION

14. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 13 and for their Third Cause of Action state as follows.

15. That Defendant is strictly liable in that it developed, marketed, produced, manufactured, distributed and sold an inherently dangerous and defective drug, to-wit Bendectin, which it knew or should have known could cause injuries and defects in children such as said Minor upon ingestion during pregnancy, while failing to test or inadequately testing the potential birth defect producing effects upon ingestion during

pregnancy and failing to warn the users of Bendectin of the potential birth defect producing effects upon ingestion during pregnancy.

16. That the foregoing acts and omissions of the Defendant directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment, and Plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson, as parents of Jessica Elizabeth Thompson, a Minor, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Larry James Christopher Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Donna Lynn Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

#### FOURTH CAUSE OF ACTION

17. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 16 and for their Fourth Cause of Action state as follows.

18. That the applicable Federal law covering the manufacturing and distributing of drugs during the time period in controversy was the Federal Food, Drug and Cosmetics Act passed by the 7th Congress on June 25, 1938, and cited as 52 Stat 1040, as amended.

19. That the purpose of 52 Stat 1040, among other purposes, was to prohibit the movement in Interstate Commerce of misbranded drugs.

20. That per § 201(n) of 52 Stat 1040, the determination as to whether a drug is misbranded includes "not only

representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences, which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary and usual".

21. That Defendant did not at any time during the time period in controversy, reveal or attempt to reveal any facts material to consequences which may result in the unborn offspring of mothers receiving the drug in question for indications relating to pregnancy.

22. That pursuant to § 502(a) of 52 Stat 1040, a drug is deemed misbranded if its labeling is false or misleading in any particular.

23. That pursuant to § 502(f)(2) of 52 Stat 1040, a drug is deemed misbranded unless its labeling bears "such adequate warning against use in those pathologic conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods, or duration of administration or application, in such manner and form, as are necessary for the protection of users".

24. That pursuant to § 502(j) of 52 Stat 1040, a drug is deemed misbranded if it is "dangerous to health when used in the dosage, or with the frequency of duration prescribed, recommended or suggested in the labeling thereof".

25. That the promotion of said drug, Bendectin, by the Defendant for the use in females during the time period in controversy, without revealing or attempting to reveal any facts material to consequences which may result in the unborn offspring of mothers receiving the drug, constituted misbranding of said pharmaceutical drug per sub-sections (a), (f)(2) and (j) of § 502 and (n) of § 201 of 52 Stat 1040.

26. That violation of said Federal Statutes in the promotion of said drug, Bendectin, by the Defendant herein enumerated, constitutes a rebuttable presumption of negligence.

27. That the Defendant's violation of said Federal Statutes directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment, and Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as parents of Jessica Elizabeth Thompson, a Minor, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Larry James Christopher Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Donna Lynn Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

#### FIFTH CAUSE OF ACTION

28. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 27 and for their Fifth Cause of Action state as follows.

29. The Defendant has made false and fraudulent representations of fact as to the safety, nontoxicity, and freedom from side effects of its product Bendectin and those representations were made under circumstances that the said Defendant knew or should have known that they were false, or alternatively, were represented to be true while said Defendant had no knowledge as to the truth thereof and the said Defendant stood to benefit financially by its misrepresentations, active and constructive. These representations were made in promotional literature, product inserts and by detailmen to prescribing physicians. By these representations

the Defendant worked a fraud and deceit upon the consuming public, and more particularly, upon the Plaintiffs.

30. The Defendant deliberately pursued a policy of non-disclosure with regard to adverse reactions attributable to the product Bendectin, especially, but not limited to, a number of reporting physicians, each reporting that a number of mothers who used Bendectin during pregnancy gave birth to physically deformed babies. The said Defendant thereby deprived the medical community and the public and the Plaintiffs of significant facts which, if known, would have permitted an informed judgment of the drug in light of the grave risks attending its use.

31. The Defendant failed to submit all relevant data bearing on the safety of the Drug Bendectin to the Food and Drug Administration, as required by law.

32. That the acts and omissions of the Defendant, as aforementioned, directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment, and Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as parents of Jessica Elizabeth Thompson, a Minor, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Larry James Christopher Thompson, Individually, had been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Donna Lynn Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

### SIXTH CAUSE OF ACTION

33. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 32 and for their Sixth Cause of Action state as follows.

34. The foregoing acts and omissions of the Defendant were willful, wanton and grossly negligent and caused, directly and proximately, the injuries to Plaintiffs as aforementioned, all to which Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Twenty Two Million Five Hundred Thousand (\$22,500,000.00) Dollars punitive damages; Plaintiff Larry James Christopher Thompson, Individually, has been damaged in the amount of Ten Million (\$10,000,000.00) Dollars punitive damages; and Plaintiff Donna Lynn Thompson, Individually, has been damaged in the amount of Ten Million (\$10,000,000.00) Dollars punitive damages.

WHEREFORE, Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, demand Judgment against the Defendant in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages and Twenty Two Million Five Hundred Thousand (\$22,500,000.00) Dollars punitive damages; Plaintiff Larry James Christopher Thompson, Individually, demands Judgment against the Defendant in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages and Ten Million (\$10,000,000.00) Dollars punitive damages; and Plaintiff Donna Lynn Thompson, Individually, demands Judgment against the Defendant in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages and Ten Million (\$10,000,000.00) Dollars punitive damages.

Plaintiffs also demand all costs, interest and attorneys fees, and all other relief to which they may be entitled.

WAITE, SCHNEIDER, BAYLESS  
& CHESLEY CO., L.P.A.

/s/ Stanley M. Chesley  
1318 Central Trust Tower  
Cincinnati, Ohio 45202  
TRIAL COUNSEL FOR  
PLAINTIFFS

George A. Kokus  
COHEN AND KOKUS  
1521 N.W. 15th Street  
Miami, Florida 33125  
CO-COUNSEL FOR PLAINTIFFS

Allen T. Eaton  
COHEN AND KOKUS  
Washington D.C. Office  
1025 Vermont Avenue, N.W.  
Suite 503  
Washington, D.C. 20005  
CO-COUNSEL FOR PLAINTIFFS

### JURY DEMAND

The Plaintiffs herein demand a trial by jury on all issues.

/s/ Stanley M. Chesley  
TRIAL COUNSEL FOR  
PLAINTIFFS.

COURT OF COMMON PLEAS  
HAMILTON COUNTY, OHIO

Case No. A8307057

Neil Frazer MacTavish and Margaret MacTavish as Next  
Friends and Guardians of Neil MacTavish, A Minor  
49 Bells Burn Avenue, LinLithgow, Scotland

Neil Frazer MacTavish, Individually  
49 Bells Burn Avenue, LinLithgow, Scotland

Margaret MacTavish, Individually  
49 Bells Burn Avenue, LinLithgow, Scotland  
Plaintiffs,

v.

Merrell-Dow Pharmaceuticals, Inc., (formerly known as  
Richardson-Merrell, Inc.) a Delaware Corporation  
2110 East Galbraith Road, Cincinnati, Ohio 45215  
Defendant.

COMPLAINT AND JURY DEMAND

[Filed September 1, 1983]

Now come the Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish as Next Friends and Guardians of Neil MacTavish, a Minor, and Individually, and state their causes of action as follows.

FIRST CAUSE OF ACTION

1. The Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as Next Best Friends and Guardians of Neil MacTavish, a Minor, and Individually, state that they are residents of the City of LinLithgow, Country of Scotland.

2. That Defendant Merrell-Dow Pharmaceuticals, Inc.,

FDBA Merrell-National Laboratories, Division of Richardson-Merrell, Inc., is a Delaware corporation with its principal place of business in the City of Cincinnati, County of Hamilton, State of Ohio.

3. That on or about August of 1978, Plaintiff Margaret MacTavish became pregnant with Neil MacTavish.

4. That during the first trimester of said pregnancy, Margaret MacTavish began to experience nausea for which her obstetrician prescribed the drug product known as Bendectin.

5. That said product, Bendectin, is a prescription drug made and distributed by the Defendant.

6. That Neil MacTavish was born May 11, 1979 subsequent to which it became obvious that the minor suffered from multiple deformities, including but not limited to, complete absence of the right hand; both forearm bones are present, but there are no definite carpals.

7. That as a result of said abnormalities, Neil MacTavish was caused to undergo extensive medical treatment and was and will continue to be required to undergo further medical treatment.

8. That the injuries suffered by Neil MacTavish were directly and proximately caused by the administration of the drug product Bendectin to Margaret MacTavish during the first trimester of pregnancy.

9. That the negligence of the Defendant in developing, marketing, producing, manufacturing, distributing and selling a product that Defendant knew or should have known could cause injuries and defects in children such as Neil MacTavish upon ingestion during pregnancy, directly and proximately caused said injuries; that the injuries were directly and proximately caused by the negligence of the Defendant in failing to test or inadequately testing the potential birth defect producing effects upon ingestion of Bendectin during pregnancy; that injuries were caused, directly and proximately by the negligence of the Defendant in failing to warn the users of Bendectin of the potential birth defect producing effects upon ingestion during pregnancy.

10. That as a direct and proximate result of the aforementioned negligence of the Defendant, Neil MacTavish was and will be caused to suffer considerable pain and suffering and to undergo further medical treatment, and Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as parents of Neil MacTavish, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Neil Frazer MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff, Margaret MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

### SECOND CAUSE OF ACTION

11. The plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 10 and for their Second Cause of Action state as follows.

12. That Defendant expressly and impliedly warranted that its product, Bendectin, was of merchantable quality and fit and safe for its intended purposes and uses.

13. That Defendant breached said express and implied warranties of merchantability, fitness and safety and that said breach directly and proximately caused the injuries suffered by Neil MacTavish, a Minor, and that as a direct and proximate breach of the aforementioned warranties, said Minor was and will be caused to suffer considerable pain and suffering, and to undergo continuous medical treatment, and Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as parents of Neil MacTavish were and will be caused to suffer considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount

of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff, Neil Frazer MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff, Margaret MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

### THIRD CAUSE OF ACTION

14. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 13 and for their Third Cause of Action state as follows.

15. That Defendant is strictly liable in that it developed, marketed, produced, manufactured, distributed and sold an inherently dangerous and defective drug, to-wit Bendectin, which it knew or should have known could cause injuries and defects in children such as said Minor upon ingestion during pregnancy, while failing to test or inadequately testing the potential birth defect producing effects upon ingestion during pregnancy and failing to warn the users of Bendectin of the potential birth defect producing effects upon ingestion during pregnancy.

16. That the foregoing acts and omissions of the Defendant directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment, and Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as parents of Neil MacTavish, a Minor, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Neil Frazer MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Margaret MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

#### FOURTH CAUSE OF ACTION

17. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 16 and for their Fourth Cause of Action state as follows.

18. That the applicable Federal law covering the manufacturing and distributing of drugs during the time period in controversy was the Federal Food, Drug and Cosmetics Act passed by the 7th Congress on June 25, 1938, and cited as 52 Stat 1040, as amended.

19. That the purpose of 52 Stat 1040, among other purposes, was to prohibit the movement in Interstate Commerce of misbranded drugs.

20. That per § 201(n) of 52 Stat 1040, the determination as to whether a drug is misbranded includes "not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences, which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary and usual".

21. That Defendant did not at any time during the time period in controversy, reveal or attempt to reveal any facts material to consequences which may result in the unborn offspring of mothers receiving the drug in question for indications relating to pregnancy.

22. That pursuant to § 502(a) of 52 Stat 1040, a drug is deemed misbranded if its labeling is false or misleading in any particular.

23. That pursuant to § 502(f)(2) of 52 Stat 1040, a drug is deemed misbranded unless its labeling bears "such adequate warning against use in those pathologic conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods, or duration of administration or application, in such manner and form, as are necessary for the protection of users".

24. That pursuant to § 502(j) of 52 Stat 1040, a drug is deemed misbranded if it is "dangerous to health when used in the dosage, or with the frequency of duration prescribed, recommended or suggested in the labeling thereof".

25. That the promotion of said drug, Bendectin, by the Defendant for the use in females during the time period in controversy, without revealing or attempting to reveal any facts material to consequences which may result in the unborn offspring of mothers receiving the drug, constituted misbranding of said pharmaceutical drug per sub-sections (a), (f)(2) and (j) of § 502 and (n) of § 201 of 52 Stat 1040.

26. That violation of said Federal Statutes in the promotion of said drug, Bendectin, by the Defendant herein enumerated, constitutes a rebuttable presumption of negligence.

27. That the Defendant's violation of said Federal Statutes directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment, and Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as parents of Neil MacTavish, a Minor, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Neil Frazer MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Margaret MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

#### FIFTH CAUSE OF ACTION

28. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 27 and for their Fifth Cause of Action state as follows.

29. The Defendant has made false and fraudulent representations of fact as to the safety, nontoxicity, and freedom from side effects of its product Bendectin and those representations were made under circumstances that the said Defendant knew or should have known that they were false, or alternatively, were represented to be true while said Defendant had no knowledge as to the truth thereof and the said Defendant stood to benefit financially by its misrepresentations, active and constructive. These representations were made in promotional literature, product inserts and by detailmen to prescribing physicians. By these representations the Defendant worked a fraud and deceit upon the consuming public, and more particularly, upon the Plaintiffs.

30. The Defendant deliberately pursued a policy of non-disclosure with regard to adverse reactions attributable to the product Bendectin, especially, but not limited to, a number of reporting physicians, each reporting that a number of mothers who used Bendectin during pregnancy gave birth to physically deformed babies. The said Defendant thereby deprived the medical community and the public and the Plaintiffs of significant facts which, if known, would have permitted an informed judgment of the drug in light of the grave risks attending its use.

31. The Defendant failed to submit all relevant data bearing on the safety of the drug Bendectin to the Food and Drug Administration, as required by law.

32. That the acts and omissions of the Defendant, as aforementioned, directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment, and Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as parents of Neil MacTavish, a Minor, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compen-

satory damages; Plaintiff Neil Frazer MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Margaret MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

### SIXTH CAUSE OF ACTION

33. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 32 and for their Sixth Cause of Action state as follows.

34. The foregoing acts and omissions of the Defendant were willful, wanton and grossly negligent and caused, directly and proximately, the injuries to Plaintiffs as aforementioned, all to which Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Twenty Two Million Five Hundred Thousand (\$22,500,000.00) Dollars punitive damages; Plaintiff Neil Frazer MacTavish, Individually, has been damaged in the amount of Ten Million (\$10,000,000.00) Dollars punitive damages; and Plaintiff Margaret MacTavish, Individually, has been damaged in the amount of Ten Million (\$10,000,000.00) Dollars punitive damages.

WHEREFORE, Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, demand Judgment against the Defendant in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages and Twenty Two Million Five Hundred Thousand (\$22,500,000.00) Dollars punitive damages; Plaintiff Neil Frazer MacTavish, Individually, demands Judgment against the Defendant in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages and Ten Million (\$10,000,000.00) Dollars punitive damages; and Plaintiff Margaret MacTavish, Individually, demands Judgment against the Defendant in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages and Ten

Million (\$10,000,000.00) Dollars punitive damages. Plaintiffs also demand all costs, interest and attorneys fees, and all other relief to which they may be entitled.

WAITE, SCHNEIDER, BAYLESS  
& CHESLEY CO., L.P.A.

/s/ STANLEY M. CHESLEY  
1318 Central Trust Tower  
Cincinnati, Ohio 45202  
TRIAL COUNSEL FOR PLAINTIFFS

George A. Kokus  
COHEN AND KOKUS  
1521 N.W. 15th Street Road  
Miami, Florida 33125  
CO-COUNSEL FOR PLAINTIFFS

Allen T. Eaton  
COHEN AND KOKUS  
Washington D.C. Office  
1025 Vermont Avenue, N.W.  
Suite 503  
Washington, D.C. 20005  
CO-COUNSEL FOR PLAINTIFFS

### JURY DEMAND

The Plaintiffs herein demand a trial by jury on all issues.

/s/ STANLEY M. CHESLEY  
TRIAL COUNSEL FOR PLAINTIFFS

## IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO WESTERN DIVISION

CIVIL NO. MDL #486

### IN RE: "BENDECTIN" PRODUCTS LIABILITY LITIGATION

### ORDER

[Filed August 24, 1985]

This matter is before the Court on various Plaintiffs' Motions to Remand and upon a *sua sponte* consideration of this Court's jurisdiction prompted by a recent reversal of a prior order denying a motion to remand. *Thompson v. Merrell Dow Pharmaceuticals, Inc.*, No. 84-3418 slip op. (July 15, 1985). Based on that Sixth Circuit opinion and an opinion by the Honorable S. Arthur Spiegel in *Griffin v. O'Neal, Jones & Feldman, Inc.*, 604 F. Supp. 717 (S.D. Ohio 1985), all Ohio plaintiffs shall be dismissed and all cases removed from Ohio state courts shall be remanded as outlined below.

Subject matter jurisdiction cannot be waived and can be raised at any time in the life of a case. Fed. R. Civ. P. 12(h)(3). Plaintiffs invoke this Court's jurisdiction under two of the statutory grants — 28 U.S.C. §§ 1331, 1332. (Doc. no. 1672) In addition, defendant relies on § 1331 as the basis for this Court's removal jurisdiction. (Doc. no. 1016 at 3)

The "arising under" jurisdiction of § 1331 was succinctly defined in a recent United States Supreme Court opinion.

"Under our interpretations, Congress has given the lower federal courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a well-pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right

to relief necessarily depends on resolution of a substantial question of federal law.”

*Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1, 27-28 (1983).

Judge Spiegel has ruled recently, after a comprehensive analysis, that the Food, Drug and Cosmetic Act does not create or imply a private cause of action for persons injured as a result of violation of that act. *Griffin, v. O'Neal, Jones & Feldman, Inc.*, 604 F. Supp. 717 (S.D. Ohio 1905). Defendant apparently conceded this point before the Sixth Circuit. *Thompson v. Merrell Dow Pharmaceuticals, Inc.*, slip op. at 3. Further, the Sixth Circuit rejected defendant's position that plaintiffs' right to relief necessarily depends on resolution of a substantial question of federal law. *Id.* The jurisdiction of this Court over these cases cannot, therefore, rest on 28 U.S.C. § 1331.

Nor can this Court's jurisdiction rest on 28 U.S.C. § 1332. Defendant is a citizen of Ohio as its principal place of business is Ohio. *Id.* § 1332(c). As such, defendant does not share a diversity of citizenship with those plaintiffs who are also citizens of Ohio. Defendant has conceded this lack of diversity jurisdiction. (Doc. no. 1016 at 3 & n.5).

The result of the above analysis is that the Court does not have jurisdiction over the complaints brought by Ohio plaintiffs and over the cases removed from Ohio state courts. See also 28 U.S.C. § 1441(b). Fed. R. Civ. P. 21 states that “[m]isjoinder of parties is not ground for dismissal of an action. Parties may be dropped or added by order of the court on motion of any party or of its own initiative at any stage of the action and on such terms as are just.” This rule gives the Court the power to perfect its diversity jurisdiction by dismissing nondiverse parties provided that those nondiverse parties are not indispensable under Fed. R. Civ. P. 19. *Sams v. Beech Aircraft Corp.*, 625 F.2d 273, 277 (9th Cir. 1980). The Ohio plaintiffs herein are not of the type described in Rule 19.

As to those plaintiffs removed here from Ohio courts, 28 U.S.C. § 1447(c) provides that if at any time prior to final judgment “it appears that the case was removed improvidently and without jurisdiction, the district court shall remand the case . . . .” Final judgment has not yet been entered in this case as a Rule 59 motion is pending. See Fed. R. App. P. 4. See e.g., *Live and Let Live, Inc. v. Carlsberg Mobile Home Properties, Ltd.*, 592 F.2d 846 (5th Cir. 1979).

In accordance with the foregoing, Ohio plaintiffs filing their complaints in Ohio district court: shall be DISMISSED without prejudice. A list of those cases and plaintiffs appear in Appendix A. All cases removed from Ohio state courts under 28 U.S.C. § 1441 shall be REMANDED to the courts from which they came. Those cases appear listed in Appendix B.

IT IS SO ORDERED.

/s/ Carl B. Rubin, Chief Judge  
United States District Court

**APPENDIX A**  
Residents of Ohio

<b>CASE NO.</b>	<b>CASE NAME</b>
C-1-81-069	Robbin Eugene Thomas et al.
C-1-82-546	Donald McCune et al.
C-1-82-657	Barbara Twain
C-1-82-789	Robert Faraday et al.
C-1-82-963	Joseph Felhaus
C-1-82-964	Irving Posenstein et al.
C-1-82-1039	Kimberly Wykoff et al.
C-1-82-1343	Charles Schneider et al.
C-1-82-1360	Charles Wilfert
C-1-83-121	Donald Drechsler
C-1-83-606	Valerie Johnson
C-1-83-1018	John Richard Noe et al.
C-1-83-1022	Dennis Valentine
C-1-83-1185	Philip Balsamo et al.
C-1-83-1186	Charles Hubbard et al.
C-1-83-1187	Charles Robinson et al.
C-1-83-1188	Rosemary Reyland
C-1-83-1190	Glen Wright et al.
C-1-83-1240	Lawrence Meyers et al.
C-1-83-1474	Daniel Eckert Behrens et al.
C-1-83-1438	Peter Sargeant
C-1-83-1625	Michael Wright
C-1-83-1713	Randall K. Weber
C-1-83-1802	Robert Matthews
C-1-83-1803	Gail C. Craft
C-1-83-1848	Robert Parker
C-1-83-1915	John Doe
C-1-84-0034	George Luis Rivera et al.
C-1-84-0134	Mark E. Leyendecker et al.
C-1-84-0094	Tina Lynn Schaefer
C-1-84-0136	Millard Mach
C-1-84-0095	Donald Thieken
C-1-84-0096	Joseph A. Del Balso
C-1-84-0137	Edward F. Graham

C-1-84-0170	Sandra Becker
C-1-84-0164	David Hackenberry
C-1-84-0178	Steven Garrett et al.
C-1-84-0260	Delores Appling
C-1-84-0307	Dale Edward Cahall et al.
C-1-84-0311	Anthony William Strunks et al.
C-1-84-0336	Ronald Stone et al.
C-1-84-0340	Douglas Cox et al.
C-1-84-0371	Mark Lukic et al.
C-1-84-0372	Janet Getz et al.
C-1-84-0504	Joseph Glen LaPaglin et al.
C-1-84-0595	Carrie Blue Fletcher et al.
C-1-84-0900	Gregory Koritansky et al.
C-1-84-0901	Patricia West et al.
C-1-84-0955	Charles Eberhardt et al.
C-1-84-1009	Seth A. Wilkinson et al.
C-1-84-1215	Randle J. Perry et al.
C-1-84-1293	Sherry A. Foster et al.
C-1-84-1303	Clayton M. Rust et al.
C-1-84-1307	James G. Sinclair
C-1-84-1308	David Bryan Saltsman et al.
C-1-84-1415	David Parker
C-1-84-1424	Dennis Kombrinch et al.
C-1-84-1485	Robert John Appel et al.
C-1-84-1486	Richard Cole et al.
C-1-84-1497	John Kenneth Basalygo et al.
C-1-84-1497	David M. Beiersdorfer
C-1-84-1497	Leonard Anthony Bleh
C-1-84-1497	Molly Jean Bradbury
C-1-84-1497	Charles A. Cerino
C-1-84-1497	Marion Clayton
C-1-84-1497	John Conelly
C-1-84-1497	Jesse Erkins et al.
C-1-84-1497	Robert Martin Geist et al.
C-1-84-1497	David Lee Highben
C-1-84-1497	Keith Hungler et al.
C-1-84-1497	Thomas Irving Jordan
C-1-84-1497	Donald Lindeman et al.

C-1-84-1497 Steven George Lowe  
 C-1-84-1497 John Michael Lucius  
 C-1-84-1497 Bruce Alvin Reed et al.  
 C-1-84-1497 Alvin Ward Scales  
 C-1-84-1497 Thomas Raymond Schneider  
 C-1-84-1497 Scott Thompson et al.  
 C-1-84-1497 Frank Watson et al.  
 C-1-84-1499 Michael R. Oliver et al.  
 C-1-84-1500 Melessa Beel et al.  
 C-1-84-1501 Billy Joel Watkins et al.  
 C-1-84-1502 Deborah A. Jones  
 C-1-84-1503 Aric D. McKee  
 C-1-84-1522 Richard J. Caddell  
 C-1-84-1557 Carolyn S. Shuff  
 C-1-84-1608 Edward Armstrong  
 C-1-84-1614 Billie J. Burton  
 C-1-84-1665 Earl Gibson et al.  
 C-1-84-1665 Timothy Ray Haar et al.  
 C-1-84-1665 Joseph Edward Nourse  
 C-1-84-1665 Horace Eugene Ralston  
 C-1-84-1665 Gerald Norman Springer  
 C-1-84-1665 Daniel Allard Uhl  
 C-1-84-1698 Timothy Alan Guthru et al.  
 C-1-84-1706 Tiffany Lynn Lofties  
 C-1-84-1707 Matthew J. Armstrong  
 C-1-84-1708 Joseph Ryan Lorenzo  
 C-1-84-1773 Michael Barker et al.  
 C-1-84-1774 Charles Jones Sr. et al.  
 C-1-84-1813 Roger F. Miller et al.  
 C-1-84-1814 John R. Green et al.  
 C-1-84-1821 Carolyn Ann Shaw et al.  
 C-1-84-1889 Ruth M. Biggs et al.  
 C-1-84-1915 Vivian Lee Davis et al.  
 C-1-84-1915 Deborah Elaine Frye et al.  
 C-1-84-1915 Boyd Jerome Graves  
 C-1-84-1915 Steven David Knapp et al.  
 C-1-84-1915 John Farrel Perkins et al.  
 C-1-84-1915 Ronald S. Pretekin et al.

C-1-84-1915 Craig Douglas Tuner  
 C-1-84-1916 Robert Francis Eder  
 C-1-85-0002 Dana Patrick Connolly et al.  
 C-1-85-0002 William P. Drozda et al.  
 C-1-85-0002 Jesse James Erkins et al.  
 C-1-85-0002 David Joseph Innes et al.  
 C-1-85-0002 William V. Jackson et al.  
 C-1-85-0002 Charles Stephen Marshall  
 C-1-85-0002 Russell Rosen  
 C-1-85-0016 Jon P. Roberts  
 C-1-85-0018 Nevil Ray Curry  
 C-1-85-0018 Patricia M. West  
 C-1-85-0018 Stephen A. Kendall et al.  
 C-1-85-0018 David W. Miller  
 C-1-85-0018 Michael Prince  
 C-1-85-0018 Anthony Arthur Williams Sr., et al.  
 C-1-85-0055 Fred W. Baritell Jr. et al.  
 C-1-85-0055 Rodney Goffinet et al.  
 C-1-85-0055 Guillermo C. Guerigiendo et al.  
 C-1-85-0055 Thomas Lee Levi et al.  
 C-1-85-0055 James Alan Peach  
 C-1-85-0055 James Robinson et al.  
 C-1-85-0055 Thomas Joseph Thole  
 C-1-85-0055 Timothy J. Waugh  
 C-1-85-0055 Lonny Lee Wilson  
 C-1-85-0061 Melissa L. Rosebury et al.  
 C-1-85-0106 Mark W. Delp  
 C-1-85-0110 Bruce Braddock  
 C-1-85-0118 Ross Robert Burton  
 C-1-85-0123 Angela Droste  
 C-1-85-0127 Janet Ciepps et al.  
 C-1-85-0128 Wanda Castro  
 C-1-85-0129 Karl Woods  
 C-1-85-0130 John Howell  
 C-1-85-0131 John Howell  
 C-1-85-0136 Joyce Marie Wallace et al.  
 C-1-85-0138 Eileen Elfers et al.  
 C-1-85-0139 William F. Downey et al.

C-1-85-0139 Louis Richard Kroner III et al.  
 C-1-85-0139 Michael E. Laage  
 C-1-85-0139 Charles E. Neal  
 C-1-85-0139 Charles M. Sidwell  
 C-1-85-0139 Linda L. Wagner  
 C-1-85-0140 Sandra B. Jarman  
 C-1-85-0143 David A. Stefek et al.  
 C-1-85-0167 Jennifer Gerau  
 C-1-85-0188 Marvin Leslie Montgomery et al.  
 C-1-85-0197 Richard Frank Lawwell Jr.  
 C-1-85-0200 Henry L. Bank et al.  
 C-1-85-0200 Patricia Ann Stewart Ford  
 C-1-85-0200 Stephen Wesley Poch Jr.  
 C-1-85-0200 Dwight Bradley Dodrill  
 C-1-85-0205 Deborah Mohn  
 C-1-85-0207 Marlene Bettencourt  
 C-1-85-0209 Timothy Michael Brown  
 C-1-85-0224 David S. Soell  
 C-1-85-0225 Thomas M. Murray  
 C-1-85-0226 Joseph Christian Bang et al.  
 C-1-85-0227 Billy Joe Johnson  
 C-1-85-0228 Barbara Wallace  
 C-1-85-0237 Ronald Kohlrieser  
 C-1-85-0244 Clarence Freeman et al.  
 C-1-85-0244 Inez Peck Spencer et al.  
 C-1-85-0256 David Parker  
 C-1-85-0258 R. Marc Sternberg  
 C-1-85-0269 Diana Klein  
 C-1-85-0271 Danny Edward Harrison  
 C-1-85-0277 James R. Rice et al.  
 C-1-85-0279 Michelle Meckanics  
 C-1-85-0280 Peggy Schoonover  
 C-1-85-0282 Evelyn Carol Bell  
 C-1-85-0282 Charles J. Fritsch Sr. et al.  
 C-1-85-0282 William Lyle Havens  
 C-1-85-0282 John Tomaselli et al.  
 C-1-85-0286 Kevin Colin Prather et al.  
 C-1-85-0287 Dena Abdalla

C-1-85-0288 Brandon Lee McCroskey  
 C-1-85-0290 Steven Dale Smith  
 C-1-85-0304 Wagih S. Neirievz  
 C-1-85-0307 Jennifer Deborde et al.  
 C-1-85-0308 David E. Meek et al.  
 C-1-85-0309 Kyle D. Dart  
 C-1-85-0310 Bethany Blaha  
 C-1-85-0311 Heather Black  
 C-1-85-0312 Scott Herskovic  
 C-1-85-0313 Victoria Samayon  
 C-1-85-0314 Jean L. Kalt  
 C-1-85-0315 Kellee Ann Love  
 C-1-85-0316 Michael D. Valeries Sr. et al.  
 C-1-85-0318 David Curtis  
 C-1-85-0318 Ronald Kroninak  
 C-1-85-0319 Carol Linda Curtis  
 C-1-85-0320 Geraldine Roserie  
 C-1-85-0321 Robert Carl DeHaven  
 C-1-85-0328 Linda L. Benton  
 C-1-85-0335 Everett Rogers et al.  
 C-1-85-0342 Lynne G. Gamble  
 C-1-85-0344 Wanda Jo Brown et al.  
 C-1-85-0346 Donald Dale Bauer  
 C-1-85-0347 Patricia Ann Ford  
 C-1-85-0347 Conrad P. Foss  
 C-1-85-0347 William Oldham II  
 C-1-85-0347 Stephen Polk  
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 C-1-85-0373 Dennis Roy Assenmacher et al.  
 C-1-85-0416 Mark Ryan Mitchell  
 C-1-85-0505 Dale Allen Sollts  
 C-1-85-0572 Michael Huseman  
 C-1-85-0577 Elizabeth L. Newman  
 C-1-85-0579 Jerome L. Heckman  
 C-1-85-0606 Patrick Pratt  
 C-1-85-0607 Danny Wayne Brown  
 C-1-85-0611 Annette Williams

C-1-85-0612	Charles S. Sprow
C-1-85-0613	Shawn Beggs
C-1-85-0613	Robert P. Bulan
C-1-85-0613	Don R. Burton
C-1-85-0613	Wayne E. Dearwester

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**CASE NO.**

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C-1-83-1436	C-1-84-1788	C-1-85-539
C-1-83-1437	C-1-85-161	C-1-85-540
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C-1-84-1301	C-1-85-161	C-1-85-552
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C-1-84-1426	C-1-85-300	C-1-85-624
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C-1-84-1616	C-1-85-512	
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C-1-84-1727	C-1-85-514	
C-1-84-1749	C-1-85-515	

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IN THE  
**Supreme Court of the United States**  
OCTOBER TERM, 1985

MERRELL DOW PHARMACEUTICALS, INC.,  
*Petitioner,*

v.

LARRY JAMES CHRISTOPHER THOMPSON and DONNA  
LYNN THOMPSON as Next Friends and Guardians of  
JESSICA ELIZABETH THOMPSON, LARRY JAMES CHRIS-  
TOPHER THOMPSON, Individually, and DONNA LYNN  
THOMPSON, Individually, *et al.*,  
*Respondents.*

**RESPONDENTS' BRIEF IN OPPOSITION TO  
PETITION FOR A WRIT OF CERTIORARI TO  
THE UNITED STATES COURT OF APPEALS  
FOR THE SIXTH CIRCUIT**

STANLEY M. CHESLEY  
WAITE, SCHNEIDER, BAYLESS & CHESLEY  
1513 Central Trust Tower  
Fourth and Vine Streets  
Cincinnati, Ohio 45202  
(513) 621-0267

*Counsel for Respondents*

*Of Counsel:*

ALLEN T. EATON  
ALLEN T. EATON & ASSOCIATES  
1029 Vermont Avenue, N.W.  
Washington, D.C. 20005

FELICIA C. SMITH  
LAW OFFICES OF GEORGE A. KOKUS  
1521 N.W. 15th Street Road  
Miami, Florida 33125

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IN THE  
**Supreme Court of the United States**

OCTOBER TERM, 1985

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No. 85-619

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MERRELL DOW PHARMACEUTICALS, INC.,  
*Petitioner,*

v.

LARRY JAMES CHRISTOPHER THOMPSON and DONNA  
LYNN THOMPSON as Next Friends and Guardians of  
JESSICA ELIZABETH THOMPSON, LARRY JAMES CHRIS-  
TOPHER THOMPSON, Individually, and DONNA LYNN  
THOMPSON, Individually, *et al.*,  
*Respondents.*

---

**RESPONDENTS' BRIEF IN OPPOSITION TO  
PETITION FOR A WRIT OF CERTIORARI TO  
THE UNITED STATES COURT OF APPEALS  
FOR THE SIXTH CIRCUIT**

---

**STATEMENT OF THE CASE**

This case arises on a Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit filed by petitioner Merrell Dow Pharmaceuticals, Inc. (hereinafter referred to as Merrell Dow). Merrell Dow is a pharmaceutical manufacturer incorporated in Delaware with its principal place of business in Hamilton County, Ohio (Petitioner's Ap-

pendix at 13a, 23a).<sup>1</sup> Respondents are parents and children who are citizens and residents of the United Kingdom and Canada (Pet. App. at 13a, 23a).

Respondents originally filed their complaints in the Court of Common Pleas of Hamilton County, Ohio (Pet. App. at 12a, 23a). The gravamen of the complaints is that the children were born with multiple deformities as a result of their mother's ingestion of the drug Bendectin, which was developed, tested, promoted, manufactured and sold by Merrell Dow for the relief of nausea during pregnancy (Pet. App. at 13a, 23a). At all times relevant hereto, the development, testing, promotion and manufacture of Bendectin either took place in Hamilton County, Ohio, or was directed from Hamilton County, Ohio.

Each complaint consists of six causes of action, all of which are predicated on traditional state-created theories of tort liability, namely, negligence, strict liability, breach of warranty, fraud and misrepresentation. The fourth causes of action in the complaints allege that Merrell Dow violated specific provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321, *et seq.* (hereinafter FDCA), and that the violation of the federal statute "constitutes a rebuttable presumption of negligence" (Pet. App. at 16a, 26a).

Pursuant to 28 U.S.C. § 1441, petitioner removed the actions to the district court where they were consolidated with several hundred other cases. Respondents moved to remand the actions to state court pursuant to 28 U.S.C. § 1447(c) on the grounds that the claims do not provide a basis for federal question jurisdiction under 28 U.S.C. § 1331 and that removal

<sup>1</sup> Hereinafter referred to as "Pet. App."

on the basis of diversity of citizenship was prohibited by 28 U.S.C. § 1441(b), because petitioner is a citizen of Ohio (Respondents' Appendix at 1a-9a) (herein after referred to as "Resp. App.>").

The district court denied respondents' motion to remand on the ground that the fourth causes of action of respondents' complaints arise under the laws of the United States and granted petitioner's motion to dismiss the actions on the ground of *forum non conveniens* (Pet. App. at 5a, 7a).

Respondents appealed and the United States Court of Appeals for the Sixth Circuit reversed and remanded the cases to the district court with instructions to remand them to state court. The Court of Appeals based its decision in part on this Court's holding in *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983) (hereinafter referred to as "*Franchise Tax Board*"), which it quoted as follows:

Under our interpretations, Congress has given the lower courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a well-pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law.

(Pet. App. at 2a, 3a).

The Court of Appeals found federal law does not create respondents' fourth causes of action because, as the parties agree, the FDCA does not create or imply a private right of action for individuals injured as a result of violations of the FDCA. It further found

that respondents' causes of action referred to the FDCA merely as one available criterion for determining whether petitioner was negligent and, therefore, respondents' right to relief did not necessarily depend on resolution of a substantial question of federal law. Based upon these findings, the Sixth Circuit held that the causes of action did not arise under federal law and were improperly removed to federal court (Pet. App. at 3a).

### ARGUMENT

#### I. There Is No Conflict Between The Decision Of The Circuit Court And This Court's Decision In *Franchise Tax Board*

Petitioner alleges at length that there is a conflict between the circuit court's decision in this case and this Court's opinion in the case of *Franchise Tax Board v. Construction Laborers' Vacation Trust*, 463 U.S. 1 (1983). This assertion flows from a strained reading of the *Franchise Tax Board* case and a misunderstanding of the circuit court's holding.

In *Franchise Tax Board*, this Court set forth the criteria for determining if a case arises under the laws of the United States, thereby making exercise of federal jurisdiction appropriate. In doing so, this Court utilized a two-pronged test as follows:

Under our interpretations, Congress has given the lower federal courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a *well-pleaded* complaint establishes either that *federal law creates the cause of action* or that the plaintiff's right to relief necessarily depends on resolution of a *substantial question of federal law*.

*Id.* at 2856 (emphasis added).

Therefore, one of two threshold requirements must be met before a federal court may exercise jurisdiction over a state common law action, absent any other basis for jurisdiction. These threshold requirements are a well-pleaded complaint which establishes either that (a) federal law creates a cause of action or (b) plaintiff's right to relief necessarily depends on a substantial question of federal law. Neither basis for the exercise of federal jurisdiction is present in the instant case.

#### A. The FDCA does not create a private cause of action

Petitioner admits that the FDCA does not create a private cause of action.<sup>2</sup> It could not do otherwise for the legislative history of the FDCA makes it clear that Congress considered creating private causes of action prior to enacting the FDCA, but expressly refrained from doing so.<sup>3</sup>

Thus, unlike the ERISA Act considered by this Court in the *Franchise Tax Board* case, which provided for private suits by certain enumerated parties, Congress specifically considered creating private actions under the FDCA, but decided *not* to do so.

Nevertheless, petitioner has attempted to sidestep the clear legislative history of the FDCA and asserts,

<sup>2</sup> In the case at bar, it was uncontested that the Federal Food, Drug and Cosmetic Act does not provide a private right of action for its violation (footnote omitted). Thus, federal law does not "create" the cause of action.

Petition for Writ of Certiorari, p. 7.

<sup>3</sup> See *Hearings on S. 1944 Before a Subcommittee of the Commerce, U.S. Senate, 73rd Cong., 2d Sess. 10, 114, 219, 403, 431, 444 (1933).*

albeit obliquely, that there is an implied right of action under the FDCA. This argument is equally specious.

If federal law expressly creates a remedy, federal subject matter jurisdiction will almost always be found. *See, e.g., Feibelman v. Packard*, 109 U.S. 421 (1883).

If a federal law creates a duty without creating a corresponding remedy, the court must determine whether a federal remedy can be implied from the duty so as to confer federal question jurisdiction. *See Cort v. Ash*, 422 U.S. 66 (1975); *Jackson Transit Authority v. Local Division 1285, Amalgamated Transit Union*, 457 U.S. 15 (1982).

The FDCA does not create a private right of action, and the courts have uniformly refused to imply a corresponding monetary remedy for individuals injured as a result of the breach of duty prescribed by the FDCA. *National Women's Health Network, Inc. v. A. H. Robbins, Inc.*, 545 F.Supp. 1177, 1179 (D.Mass. 1982); *Gelley v. Astra Pharmaceutical Products, Inc.*, 466 F.Supp. 182, 186 (D.Minn. 1979), *aff'd* 610 F.2d 558 (8th Cir. 1979); *Pacific Trading Company v. Wilson & Co., Inc.*, 547 F.2d 367 (7th Cir. 1976); *State of Florida ex rel. Broward County v. Eli Lilly & Co.*, 329 F.Supp. 364 (S.D. Fla. 1971); *Cross v. Board of Supervisors of San Mateo County*, 326 F.Supp. 634, 638 (N.D.Cal. 1968), *aff'd* 442 F.2d 362 (9th Cir. 1971); *Clairol, Inc. v. Suburban Cosmetics and Beauty Supply, Inc.*, 278 F.Supp. 859 (N.D.Ill. 1968).

The standards for determining the availability of an implied right of action were articulated by this Court in *Cort v. Ash*, 422 U.S. at 78, and recently reiterated

in *Jackson Transit Authority*, 457 U.S. at 21-24.<sup>4</sup> In *Jackson*, the union sued the Transit Authority in federal district court for breach of a collective bargaining agreement on the ground that the district court had federal jurisdiction on the theory that Section 13(c) of the Urban Mass Transportation Act, 49 U.S.C. § 1609 (c), required that the Transit Authority guarantee the preservation of the transit workers' collective bargaining rights. This Court framed the issue as "whether Congress intended such contract actions to set forth federal, rather than state, claims," *Id.* at 21, and counseled that the process for determining the intent of Congress should begin with an analysis of the "language of the statute itself." *Id.* at 24. The Court found that neither the statute itself nor its legislative history demonstrated that Congress intended to create federal causes of action for breaches of the contracts and that, therefore, Congress intended the contracts "to be governed by state law applied in state courts." *Id.* at 29.

Applying the standards articulated by the Supreme Court for determining the availability of an implied right of action, federal courts have examined the language of the FDCA itself and the legislative history of the FDCA to discern whether Congress intended to provide a monetary remedy to a private person injured as a result of violations of the FDCA. *National Women's Health Network, Inc. v. A. H. Robbins, Inc.*, 545 F.Supp. at 1179-80; *State of Florida ex rel. Bro-*

<sup>4</sup> *See also Nieto-Santos v. Fletcher Farms*, No. 83-2119 (9th Cir. July 3, 1984) (also applying the standards articulated by this Court in *Cort v. Ash*, 422 U.S. at 78, for determining the availability of an implied right of action, held that the contract did not arise under federal law.

*ward County v. Eli Lilly & Co.*, 329 F.Supp. at 365. Section 307 of the FDCA provides that "all" proceedings for the enforcement of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337. Moreover, examination of the legislative history of the Act reveals that an express provision for a private right of action for damages was included in an early version of the Act, but was omitted from all later versions on the ground that it would create unnecessary federal action duplicative of state remedies. *Id.* at 365; *National Women's Health Network, Inc. v. A. H. Robbins, Inc.*, 545 F.Supp. at 1179.

Thus, federal courts considering the relationship between the FDCA and applicable state remedies have held that a violation of the FDCA is not an independent basis for federal question jurisdiction. *Id.* at 1178; *Gelley v. Astra Pharmaceutical Products, Inc.*, 466 F.Supp. at 187; *State of Florida ex rel. Broward County v. Eli Lilly & Co.*, 329 F.Supp. at 365-66; *Orthopedic Equipment Co. v. Eutsler*, 276 F.2d 455 (4th Cir. 1960); *Herman v. Smith, Klein and French Laboratories*, 286 F.Supp. 694 (E.D.Wis. 1968). In granting defendant's motion to dismiss plaintiff's action for lack of subject matter jurisdiction, the court in *Gelley v. Astra Pharmaceutical Products, Inc.*, held as follows:

The Courts have uniformly rejected the argument that violations of the Food, Drug and Cosmetic Act provide a civil remedy to a private individual injured as a result of the violation[s]. . . . This court agrees with these decisions and therefore holds that the Food, Drug and Cosmetic Act does not by implication provide a monetary remedy to a private person injured as a result of a violation of the act. *Cort v. Ash*, 422 U.S. 66, 95 S.Ct. 2080, 45 L.E.2d 26 (1975).

As there exists no private cause of action for a violation of the Act, there is no federal question jurisdiction. . . . As the parties are not diverse, it necessarily follows that this action must be dismissed for lack of subject matter jurisdiction.

466 F.Supp. at 186-87, *aff'd* 610 F.2d 558 (citations omitted). Respondents submit that this holding reflects the intent of Congress as evidenced in the legislative history of the FDCA.

The federal decisions referenced above are based on the premise that "a suit arises under the law that creates the cause of action." *American Wellworks v. Layne and Bowler Co.*, 241 U.S. 257, 260 (1916). This definition by Justice Holmes is entrenched in the history of the term "arising under." In accord with this rationale, in 1976 a New York federal court observed that where federal law does not replace rights granted by state law, "it is illogical to say that the litigant's claim is really predicated on a body of law which grants him no rights." *State of New York v. Local 1115 Joint Board, Nursing Home Hospital Employees Division*, 412 F.Supp. 720, 723 (E.D.N.Y. 1976). Since it is well-established that the FDCA does not create a private right of action for damages, it is "illogical" to say that respondents' fourth causes of action arise under the FDCA. Respondents' fourth causes of action are predicated on the Ohio law by way of paragraph 26 (Pet. App. at 17a, 27a). Applying the rationale of Justice Holmes, it necessarily follows that these negligence, product liability and contract actions arise under state law and should be heard in state court.

Therefore, there is no real conflict between the circuit court's decision and the first test of the appro-

priateness of removal. There is no private cause of action under the FDCA. Congress did not intend that there be private causes of action and courts have uniformly found that no private causes of action were implied. Hence, the petition for certiorari must fail unless respondents' right to relief necessarily depends on a *substantial* question of federal law.

**B. No substantial question of federal law exists**

In the instant cases, the respondents have alleged a violation of a federal safety statute, the FDCA, which, under the law of the state of Ohio, can give rise to legal liability. The common law of the state of Ohio, as in most states, has replaced the standard of care of the reasonable man with that of a safety statute where such a statute exists. Petitioner has not alleged that it was not subject to the FDCA, or that the FDCA is unconstitutional, or that the Ohio court's adoption of the FDCA, as evidence of the standard of care, is somehow violative of some legally protected right of petitioner. Petitioner only alleges that respondents, by their fourth causes of action, seek extra-territorial application of the FDCA. This defense is without merit. Respondents allege that the conduct of petitioner upon which the fourth causes of action is based occurred in Ohio and not only violates the laws of the United States but also the Ohio Pure Food and Drug Law as well.<sup>5</sup>

Indeed, the Ohio Law prohibits the manufacture of any drug which is misbranded<sup>6</sup> or which is sold with

<sup>5</sup> OHIO REV. CODE ANN. § 3715.01, *et seq.*

<sup>6</sup> OHIO REV. CODE ANN. § 3715.52(A).

false and misleading advertising.<sup>7</sup> The strictures of the Ohio Law are very similar to the FDCA.<sup>8</sup> Therefore, it is for an Ohio court to choose the standard it will utilize in determining legal culpability.

It, therefore, cannot be said that it is essential for the success of the respondents' actions that they be obliged to establish both the correctness and the applicability to their cases of the proposition of federal law. The Ohio Law furnishes an alternative basis for liability which an Ohio court is required to judicially notice.

In *Franchise Tax Board*, this Court stated as follows:

... Leading commentators have suggested that for purposes of § 1331 an action "arises under" federal law "if in order for the plaintiff to secure relief sought he will be obliged to establish both the correctness and the applicability to his case of a proposition of federal law." P. Bator, P. Mishkin, D. Shapiro, & H. Wechsler, *Hart and Wechsler's The Federal Courts and the Federal System* 889 (2d ed. 1973). . . .

*Id.* at 9. Nothing of the sort exists here. There is nothing which is absolutely essential to the respondents' cases embodied in the FDCA that is not embodied to some extent in the Ohio Law.

In short, not every remote question of the applicability of federal law rises to the dignity of a substantial

<sup>7</sup> OHIO REV. CODE ANN. § 3715.52(E).

<sup>8</sup> See OHIO REV. CODE ANN. § 3715.64 (Misbranded drug) and § 3715.68 (False advertising) (Resp. App. at 10a) and compare these sections with 21 U.S.C. § 352.

federal question calling for the unique abilities of a federal court to decide it.

For example, in *Jacobson v. New York, N.H. & H.R. Co.*, 206 F.2d 153 (1st Cir. 1953), *aff'd* 347 U.S. 909 (1954), a passenger on defendant's train filed an action brought on the theory of negligence in federal district court. The passenger's amended complaint alleged that jurisdiction was based on the existence of a question under the Federal Safety Appliance Acts, 45 U.S.C.A. §§ 1, *et seq.* On review of the district court's dismissal for lack of federal subject matter jurisdiction, the First Circuit held that the cause of action invoking the Safety Appliance Acts was not within the jurisdiction of the court under 28 U.S.C. § 1331. *Id.* at 158.

The First Circuit observed that Congress did not create a statutory right of action in favor of passengers injured as a result of violations of the Safety Appliance Acts. It noted, however, that the courts may create a right of action on the principles of the common law by regarding the breach of a penal statute as an operative fact upon which common law tort liability may be predicated, if a person injured as a result of the breach "was within the class for whose protection the penal statute was presumably passed." *Id.* at 156. The court further noted that it is "abundantly clear" that the federal courts have not, as a matter of federal common law, developed a private right of action for damages for personal injuries sustained by persons not entitled to sue under the provisions of the Federal Employers' Liability Act, 45 U.S.C. §§ 51, *et seq.* (1908), as a result of a breach of the Safety Appliance Acts. *Id.* at 157.

The court then considered the various common law principles developed by the states:

... The courts of the various states differ extensively in their formulation and application of the common law principle upon which a liability is created in favor of a person injured by breach of a criminal statute. Some courts speak of the breach as "negligence *per se*", others as "evidence of negligence" or as "prima facie evidence of negligence." Nor are they completely in agreement as to what is meant by these phrases.

*Id.* at 156. Thus, the court concluded that "[w]here there is no diversity of citizenship such an action cannot be maintained in a federal district court, since the liability for damages and the corresponding private right of action, if any, are created by state law" (citations omitted). *Id.* at 157.\*

The Supreme Court applied the same rationale in *Crane v. Cedar Rapid & Iowa City Railway Co.*, 395 U.S. 164 (1969), a suit also brought by a passenger of a railroad for injuries sustained. This Court held that the Safety Appliance Acts do not create a federal cause of action for nonemployees of a carrier and, therefore, "[t]he 'nonemployee must look for his remedy to a common law action in tort, which is to say he must sue in state court, in the absence of diversity, to implement a state cause of action'" (citations omitted). *Id.* at 166.

Both *Jacobson* and *Crane* relied heavily on the leading Supreme Court case of *Moore v. Chesapeake & O. Ry. Co.*, 291 U.S. 205 (1934). All three cases considered

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\* If a plaintiff cannot maintain a private right of action under the FDCA, it is equally obvious that the fact that plaintiffs anticipate defenses in their complaints based on federal law does not give rise to federal court jurisdiction. *Franchise Tax Board*, 463 U.S. at 10.

the relationship between a federal safety statute and state law theories of negligence and, thus, closely parallel the case at bar.

In *Moore*, the Supreme Court held that a claim invoking a federal safety statute but brought under state law does not arise under federal law. *Id.* at 21. The case was brought by an employee of the defendant railroad for injuries sustained in the course of his employment with the railroad. The first paragraph of the *Moore* complaint alleged injuries sustained while he was in interstate commerce and was brought under the Federal Employers' Liability Act, 45 U.S.C. §§ 51, *et seq.* (1908), and the Federal Safety Appliance Acts, 45 U.S.C. §§ 1, *et seq.* (1885). This Court found that these allegations set forth a federal cause of action because, under the Federal Employers' Liability Act, in connection with the Safety Appliance Acts, an employee has a private right of action. *Id.* at 210-11.

The second paragraph of the *Moore* complaint alleged the same injuries as alleged in the first paragraph, but it stated that the injuries were sustained in intrastate commerce. Although this claim invoked the Federal Safety Appliance Acts, it was brought under the Employers' Liability Act of Kentucky which prescribed the liability of common carriers for negligently causing injuries to employees while engaged in intrastate commerce. The Kentucky statute provided that an employee should not be held guilty of contributory negligence or assumption of risk where a common carrier's violation of a state or federal statute, enacted for the safety of employees, contributed to the injury or death of the employee. As to the second count of the *Moore* complaint, this Court noted:

[T]he second count of the complaint, in invoking the Federal Safety Appliance Acts, while declaring on the Kentucky Employers' Liability Act, cannot be regarded as setting up a claim which lay outside the purview of the state statute. . . . [A] violation of the acts for the safety of employees was to constitute negligence *per se* in applying the state statute and was to furnish the ground for precluding the defense of contributory negligence as well as that of assumption of risk.

*Id.* at 213. Thus, this Court held that an action brought under a state statute which brings within its scope "a breach of the duty imposed by the federal statute" is not "a suit arising under the laws of the United States." *Id.* at 214. The Court reasoned that "[t]he Federal Safety Appliance Acts, while prescribing absolute duties, and thus creating correlative rights in favor of injured employees, did not attempt to lay down rules governing actions for enforcing these rights." *Id.* at 215. In its final analysis, this Court contended that the Federal Safety Appliance Acts prescribed the duty of the carrier, but the right of the injured employee to recover damages sustained through the breach of the duty "sprang from the principles of the common law." *Id.* at 215.

In *State of Florida ex rel. Broward County v. Eli Lilly & Co.*, the district court dismissed an action brought by the state on its own behalf and on the behalf of consumers who sought monetary damages under the FDCA. Applying the standards articulated in *Moore* and its progeny, the court held the following:

There is no need to decide whether under Florida law violation of the [Federal Food, Drug and Cosmetic] Act constitutes negligence *per se*, for absent diversity a complaint that alleges common law

theories of recovery based upon the violation of a duty owed under a federal statute must be brought in a State court. *Jacobson v. New York, N.H. & H.R.R.*, 206 F.2d 153 (1st Cir. 1953), *aff'd* 347 U.S. 909, 74 S.Ct. 474 (1954); *Anderson v. Bingham & G. Ry.*, 169 F.2d 328 (10th Cir. 1948); 1 MOORE FEDERAL PRACTICE ¶ 0.60 [8.-3] (pp. 633-34).

329 F.Supp. at 366 n. 3.

The provisions of the FDCA prescribe the duties of a drug manufacturer engaged in interstate commerce but create no corresponding private right of action for damages under the FDCA. In their fourth causes of action, respondents have alleged that petitioner's violations of the FDCA constitute a rebuttable presumption of negligence. Respondents' claims invoke a federal safety act, but their right to recover damages, sustained through petitioner's alleged breach of duty, stems solely from Ohio common law principles. Thus, their claims are in fact and in substance indistinguishable from the claims brought in *Moore* and *Crane*. In relying on these Supreme Court decisions, the federal courts have uniformly refused to find federal question jurisdiction where private actions allege violations of the FDCA. Therefore, respondents are entitled to have their causes determined by the forum they originally selected.

## CONCLUSION

There is no right of action created under the Federal Food, Drug and Cosmetic Act. There is no substantial question of federal law which is essential to the success of respondents' claim. Therefore, the petition for certiorari is specious and should be denied and respondents should be awarded their costs and reasonable attorneys' fees associated with opposing a frivolous petition.

Respectfully submitted,

STANLEY M. CHESLEY

WAITE, SCHNEIDER, BAYLESS & CHESLEY  
1513 Central Trust Tower  
Fourth and Vine Streets  
Cincinnati, Ohio 45202  
(513) 621-0267

*Counsel for Respondents*

*Of Counsel:*

ALLEN T. EATON

ALLEN T. EATON & ASSOCIATES  
1029 Vermont Avenue, N.W.  
Washington, D.C. 20005

FELICIA C. SMITH

LAW OFFICES OF GEORGE A. KOKUS  
1521 N.W. 15th Street Road  
Miami, Florida 33125

## **APPENDIX**

**APPENDIX A**

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION**

**Civil Action No. A-8307057**

**NEIL FRAZER MACTAVISH, *et al.*,**

**- and -**

**LARRY JAMES CHRISTOPHER THOMPSON, *et al.*,**  
***Plaintiffs,***

**v.**

**MERRELL-DOW PHARMACEUTICALS, INC.,**  
***Defendants.***

**PLAINTIFFS' MOTION TO REMAND  
UNDER § 1447(c) FOR LACK OF JURISDICTION**

**[Filed Oct. 14, 1983]**

COME NOW the plaintiffs, by counsel, and on the basis more fully explained in the accompanying Memorandum in Support hereof, move this Court for an order remanding the above-captioned actions to the Court of Common Pleas for Hamilton County, Ohio.

Respectfully submitted,

WAITE, SCHNEIDER, BAYLESS & CHESLEY

By: /s/ JEROME L. SKINNER  
JEROME L. SKINNER (S537)

1318 Central Trust Tower  
Fourth and Vine Streets  
Cincinnati, Ohio 45202  
(513) 621-0267

2a

/s/ GEORGE A. KOKUS  
George A. Kokus, Esq.  
COHEN & KOKUS  
1521 N.W. 15th Street Road  
Miami, Florida 33125

/s/ ALLEN T. EATON (WDF)  
Allen T. Eaton, Esq.  
ALLEN T. EATON & ASSOCIATES  
1025 Vermont Avenue, N.W.  
Suite 503  
Washington, D.C. 20005

*Counsel for Plaintiffs*

3a

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

Civil Action No. A-8307057

NEIL FRAZER MACTAVISH, *et al.*,

- and -

LARRY JAMES CHRISTOPHER THOMPSON, *et al.*,  
*Plaintiffs,*

v.

MERRELL-DOW PHARMACEUTICALS, INC.,  
*Defendants.*

MEMORANDUM IN SUPPORT OF  
PLAINTIFFS' MOTION TO REMAND  
UNDER § 1447(c) FOR LACK OF JURISDICTION

I. Procedural History

Plaintiffs, residents of Scotland, filed the subject actions on September 1, 1983, in the Court of Common Pleas in Hamilton County, Ohio. On or about September 7, 1983, defendant filed a removal petition in this Court with the requisite bond. Plaintiffs, through this motion, seek an order under 28 U.S.C. § 1447(c) remanding the actions to the state court and requiring the defendants to pay plaintiffs, in accordance with 28 U.S.C. § 1446, costs and disbursements incurred by reason of the removal proceedings.

II. Operative Facts

Plaintiffs are residents of Scotland, United Kingdom, who allege that their children suffered birth defects as the result of the ingestion of Debendox during pregnancy. Debendox is the British trade name for the antinauseant morning sickness drug Bendectin manufactured by defendant Merrell. Plaintiffs allege, *inter alia*, that defendant

Merrell violated certain provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. § 301-*et seq.* (52 Stat. 1040-*et seq.*)<sup>1</sup>

In their Fourth Cause of Action, plaintiffs allege that defendant violated 21 U.S.C. § 352 when it sold Debendox (a/k/a Bendectin) in a branded and defective condition. Plaintiffs allege in paragraph 26 of their complaints that Merrell's violation of the Food, Drug and Cosmetic Act in promoting of Debendox constituted a rebuttable presumption of negligence.<sup>2</sup>

Defendants suggest that by asserting violations of the Food, Drug and Cosmetic Act, plaintiffs' claims arise under the laws of the United States, and thereby give this Court original jurisdiction under 28 U.S.C. § 1331 and provide the basis for removal under 28 U.S.C. § 1441(b).

### III. Issues Presented

#### A. Do plaintiffs' claims arise under the laws of the United States in the sense of 28 U.S.C. § 1331?

<sup>1</sup> Case numbers are A83-07057 and A83-07058. Copies of the complaints are attached hereto and incorporated herewith by reference to defendant's removal petition (Exhibit A).

<sup>2</sup> Under Ohio law, violation of a safety statute is negligence *per se*, rendering the actor liable to plaintiff if his negligence caused or contributed to causing the plaintiff's injury. Plaintiffs will amend their complaint to include this allegation.

*See Freeman v. United States*, 509 F.2d 626 (6th Cir. 1975), in which the court held that when an injury is caused by an action which violates a safety statute, which is of the kind that the statute was intended to prevent, the action constitutes negligence *per se*.

*See also Shroades v. Rental Homes, Inc.*, 68 Ohio St.2d 20, 427 N.E.2d 774 (1981); *Zehe v. Falkner*, 26 Ohio St.2d 258, 271 N.E.2d 276 (1972). Both of these cases make clear that in Ohio it is a well-settled principle of law that a violation of a specific safety statute constitutes negligence *per se*.

B. Are there any other legally cognizable grounds for removal?

C. Should the cases be removed?

### IV. Discussion

A. Allegations made in plaintiff's complaints do not provide a basis for federal question jurisdiction under 28 U.S.C. § 1331.

In asking the Court to recognize the Food, Drug and Cosmetic Act as establishing the standing of care required of a drug manufacturer, federal jurisdiction is not vested in this Court under 28 U.S.C. § 1331. In the instant case, unlike *Cort v. Ash*, 422 U.S. 66 (1975) (private right of action principles set forth by Court) plaintiffs do not assert a federal statute as the jurisdictional basis for their claims, nor do they assert that their claims arise under the federal Food, Drug and Cosmetic Act.

Moreover, it is clear that the Act does not create a private right of action. In fact, defendant has argued in open court that there is no private right of action:

MR. LEECH: Your Honor, because there's no private right of action under the statute they are citing, and the cases so hold you can't recover damages as an individual plaintiff for the violation of the statute. The only person that can bring an action for violation of this statute is the U.S. Attorney's office.

THE COURT: What statute?

MR. LEECH: The Federal Drug & Cosmetic Act, and the section on which the plaintiff relies, regardless what they prove, they can't recover under the statute as a separate cause of action.

*Oxendine v. Richardson-Merrell, Inc.*, No. 1245-82 (Superior Ct., District of Columbia, Transcript May 2, 1983, pp. 147-48) (Exhibit B).

Similarly, in the *Koller* case, defendant argued that there was no private right of action under the Food, Drug and Cosmetic Act. Defendant wrote in its Memorandum in Support of Partial Summary Judgment:

Moreover, the law is clear that there is no private cause of action under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* See, e.g., *Pacific Trading Co. v. Wilson and Co.*, 547 F.2d 367, 368 (7th Cir. 1976); *Orthopedic Equipment Co. v. Eustler*, 276 F.2d 455, 460 (4th Cir. 1960); *Keil v. Eli Lilly & Co.*, 490 F.Supp. 479 (E.D.Mich. 1980); *Gelley v. Astra Pharmaceutical Products, Inc.*, 466 F.Supp. 182, 186-187 (D. Minn. 1979), *aff'd* 610 F.2d 558 (9th Cir. 1979); *State of Florida ex rel. Broward County v. Eli Lilly & Co.*, 329 F. Supp. 364, 365-366 (S.D.Fla. 1971); *Cross v. Board of Supervisors of San Mateo County*, 326 F. Supp. 634, 638 (N.D.Cal. 1968); *aff'd* 442 F.2d 362 (9th Cir. 1971); *Clairol, Inc. v. Suburban Cosmetics and Beauty Supply, Inc.*, 278 F.Supp. 859, 860-861 (N.D.Ill. 1968).

*Koller, et al. v. Richardson-Merrell, Inc.*, No. 80-1258 (U.S. District Court for the District of Columbia, Memorandum of Defendant Richardson-Merrell Inc. In Support of Its Motion for Partial Summary Judgment Dismissing Plaintiffs' Claims for Fraud and Punitive Damages, February 5, 1982 at p. 42).

Plaintiffs' actions, to be sure, do not arise under federal law, as they do not assert a federally-created cause of action. Plaintiffs only urge that the federal Food, Drug and Cosmetic Act embodies the appropriate *standard of care* to be employed by the Ohio Court in determining if Merrell has been negligent, or if Bendectin is a defective product.

This principle of law regarding negligence *per se* has long been adopted by the courts in Ohio, and is indeed the

majority rule. W. Prosser, *Law of Torts*, § 36 (4th ed. 1971); *Restatement (Second) of Torts*, §§ 285, 286, 288B; and 39 O. Jur2d Negligence §§ 43-44 (1959).

In a recent Pennsylvania case, the United States Court of Appeals for the Third Circuit, in applying Pennsylvania law that is nearly identical to the law of Ohio on negligence *per se*, held as follows:

"Under Pennsylvania law, the violation of a governmental safety regulation constitutes negligence *per se*" if the regulation "was, in part, intended to protect the interest of another as an individual [and] the interest of the plaintiff which was invaded . . . was one which the act intended to protect. Astra cannot seriously dispute that section 130.35 [of the Code of Federal Regulations implementing provisions of the Food, Drug and Cosmetic Act] was promulgated to protect individuals such as Harrikah Stanton from precisely the type of harm that here occurred—an unexpected adverse reaction to Xylocaine. It thus would appear that Astra's failure to file the reports constituted negligence *per se*."

*Stanton v. Astra Pharmaceutical Products, Inc.*, Nos. 92-3364 and 82-3380 (3d Cir., Sept. 26, 1983, Slip Op. at 21-22) (citations omitted) (Exhibit C).

In summary, plaintiffs' claim that Merrell's violations of the Food, Drug and Cosmetic Act constitute negligence *per se* does not give rise to federal question jurisdiction under 28 U.S.C. § 1331. In the absence of federal question jurisdiction, there simply is no basis for removal under 28 U.S.C. § 1441.

Article III Courts have limited jurisdiction. In the absence of original subject matter jurisdiction in these cases, removal is improvident.

*B. There is no other legally cognizable grounds for removal.*

Defendant could contend that jurisdiction of this Court could be based on 28 U.S.C. § 1332. This argument, too, must fail. In *Pack v. Rich Terminal Company*, 502 F.Supp. 58 (S.D. Ohio 1980), Judge Spiegel held that if a defendant is a citizen of a state, removal from state court is improper.

Ohio is Merrell's principal place of business. Merrell is a corporate citizen of Ohio. Removal, therefore, is inappropriate under 28 U.S.C. § 1441(b).

After a careful review of the United States Code to discern any other bases for the exercise of jurisdiction by federal courts under the circumstances of this case, plaintiffs can find no colorable basis for the exercise of jurisdiction by an Article III Court.

*C. The cases should be remanded to state court.*

In the absence of original jurisdiction in the federal courts, there simply is no basis for removal. The cases, therefore, should be remanded to state court. Finally, plaintiffs are entitled to the payment of costs and disbursements incurred because of these removal proceedings.

Respectfully submitted,

WAITE, SCHNEIDER, BAYLESS & CHESLEY

By: /s/ JEROME L. SKINNER  
JEROME L. SKINNER (S537)

1318 Central Trust Tower  
Fourth and Vine Streets  
Cincinnati, Ohio 45202  
(513) 621-0267

/s/ GEORGE A. KOKUS  
George A. Kokus, Esq.  
COHEN & KOKUS  
1521 N.W. 15th Street Road  
Miami, Florida 33125

/s/ ALLEN T. EATON (WDF)  
Allen T. Eaton, Esq.  
ALLEN T. EATON & ASSOCIATES  
1025 Vermont Avenue, N.W.  
Suite 503  
Washington, D.C. 20005

*Counsel for Plaintiffs*

**CERTIFICATE OF SERVICE**

I hereby certify that on this the 14 day of October, 1983, a copy of the foregoing was hand-delivered to Frank C. Woodside, III, Esq., Dinsmore & Shohl, 2100 Fountain Square Plaza, 511 Walnut Street, Cincinnati, Ohio 45202.

/s/ JEROME L. SKINNER  
Jerome L. Skinner

## APPENDIX B

## § 3715.64 Misbranded drug.

(A) A drug or device is misbranded within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if:

- (1) Its labeling is false or misleading in any particular.
- (2) It is in package form and does not bear a label containing:
  - (a) In clearly legible form the name and place of business of the manufacturer, packer, or distributor;
  - (b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; but reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations prescribed by the director of agriculture.
- (3) It is a dangerous drug and does not bear a label containing in clearly legible form the name and place of business of the manufacturer of the finished dosage form and, if different, the packer or distributor.
- (4) It is a dangerous drug in finished solid oral dosage form, unless it has clearly and prominently marked or imprinted on it an individual symbol, company name, national drug code or other number, words, letters, or any combination thereof, identifying the drug and its manufacturer or distributor. This requirement does not apply to drugs that are compounded by a registered pharmacist. The manufacturer or distributor of each such drug shall make available to the state board of pharmacy descriptive material identifying the mark or imprint used by the manufacturer or distributor. The board of pharmacy shall provide this information to all poison control centers in the state. Upon application by a manufacturer or distributor, the board may exempt a drug from the requirements of this division

on the grounds that marking or imprinting such drugs is not feasible because of its size, texture, or other unique characteristic.

(5) Any word, statement, or other information required by or under authority of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, to appear on the label or labeling is not prominently placed thereon with such conspicuousness as compared with other words, statements, designs, or devices, in the labeling, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(6) It is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, cabromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, or sulphonmethane, or any chemical derivative of such substance, which derivative has been found by the director to be, and by regulations proposed by the director and adopted by the public health council designated as, habit forming, unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

(7) It is a drug and it is not designated solely by a name recognized in an official compendium unless its label bears:

- (a) The common or usual name of the drug, if any;
- (b) In case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetophenetidin, aminopyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis flucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any

derivative or preparation of any such substances, contained therein; but to the extent that compliance with these requirements is impracticable, exemptions shall be established by regulations proposed by the director and adopted by the public health council.

(8) Its labeling does not bear:

(a) Adequate directions for use;

(b) Such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary to the protection of users;

(c) Where compliance with any requirements of division (A)(8)(a) of this section, as applied to any drug or device, is not necessary for the protection of the public health, the director shall propose and the public health council shall adopt regulations exempting such drug or device from such requirements.

(9) It purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein, but the method of packing may be modified with the consent of the director. Whenever a drug is recognized in both the United States pharmacopoeia and the homeopathic pharmacopoeia of the United States, it shall be subject to the requirements of the United States pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the homeopathic pharmacopoeia of the United States, and not to those of the United States pharmacopoeia.

(10) It has been found by the director to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as required by regulations proposed by the director

and adopted by the public health council as necessary for the protection of public health. No such regulation shall be established for any drug recognized in an official compendium until the director has informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body has failed within a reasonable time to prescribe such requirements.

(11)(a) It is a drug and its container is so made, formed, or filled as to be misleading.

(b) It is an imitation of another drug.

(c) It is offered for sale under the name of another drug.

(d) The drug sold or dispensed is not the brand or drug specifically prescribed or ordered or, when dispensed by a pharmacist upon prescription, is neither the brand or drug prescribed nor a generically equivalent drug.

(12) It is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(13) It is a drug intended for use by man which:

(a) Because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a physician, dentist, veterinarian, or person licensed to prescribe any drug which, under the federal act, federal narcotic law, as defined in section 4729.02 of the Revised Code, and under sections 3715.01 to 3715.75, or Chapter 3719, of the Revised Code, may be dispensed only upon a prescription;

(b) Is limited by an effective application under section 505 of the "Federal Food, Drug, and Cosmetic Act" to use under professional supervision by a physician, dentist, or veterinarian, unless it is dispensed only:

(i) Upon a written prescription of a physician, dentist, or veterinarian;

(ii) Upon the oral prescription of a physician, dentist, or veterinarian which is reduced promptly to writing by the pharmacist;

(iii) By refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is promptly reduced to writing by the pharmacist.

(B) Any drug dispensed by filling or refilling a written or oral prescription of a physician, dentist, veterinarian, or person licensed to prescribe any drug which, under the federal act, federal narcotic law, as defined in section 4729.02 of the Revised Code, or under sections 3715.01 to 3715.75, or Chapter 3719, of the Revised Code, may be dispensed only upon a prescription shall be exempt from the requirements of this section except divisions (A)(1) and (11) of this section if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in the prescription. Unless the prescription directions prohibit labeling, the label shall include the brand name of the drug dispensed. If the drug dispensed has no brand name, the generic name and the distributor of the finished dosage form shall be included. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail.

•HISTORY: 139 v. 135. Eff 1-1-82.

The effective date provisions of § 3 of HB 135 (139 v —) read as follows:

SECTION 3. The requirement of division (A)(4) of section 3715.64 of the Revised Code that manufacturers and distributors of dangerous drugs in finished solid oral dosage form make available to the State Board of Pharmacy descriptive material identifying the mark or imprint used by the manufacturer or distributor shall not take effect until January 1, 1982. No criminal penalty shall be imposed for the manufacture, sale, or delivery, or holding or offering for sale of any misbranded drug as defined in division (A) the manufacture, sale, or delivery, or holding or offering (4) of section 3715.64 of the Revised Code unless such drug was manufactured on or after July 1, 1982.

#### § 3715.68 False advertising.

(A) An advertisement of food, drug, device, or cosmetic is false if it is false or misleading in any particular.

(B) For the purpose of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, the advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis (infantile paralysis), prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, tuberculosis, tumors, typhoid, uremia, venereal disease, is also false, except that no advertisement not in violation of division (A) of this section is false under the division if it is disseminated only to members of the medical, dental, pharmaceutical, or veterinary profession, or appears only in the scientific periodicals of these professions; provided, that whenever the director of agriculture determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the director shall propose regulations for adoption by the pub-

lic health council authorizing the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the director may deem necessary in the interests of public health; provided, that this division shall not be construed as indicating that self-medication for diseases other than those named in this section is safe or efficacious.

•HISTORY: 138 v H 965. Eff 4-9-81.

### § 3715.52 Prohibitions.

The following acts and causing them are prohibited:

(A) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;

(B) The adulteration or misbranding of any food, drug, device, or cosmetic;

(C) The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;

(D) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 3715.61 or 3715.65 of the Revised Code;

(E) The dissemination of any false advertisement;

(F) The refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by section 3715.70 of the Revised Code;

(G) The giving of a guaranty or undertaking which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of the person residing in this state from whom he received in good faith the food, drug, device, or cosmetic;

(H) The removal or disposal of a detained or embargoed article in violation of section 3715.55 of the Revised Code;

(I) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale and results in such article being misbranded;

(J) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under sections 3715.52 to 3715.72 of the Revised Code.

(K) The using, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that any application with respect to such drug is effective under section 3715.65 of the Revised Code or that such drug complies with the provisions of such section;

(L) The sale, offering for sale, giving away, or delivery at retail or to the consumer without a prescription from a physician, veterinarian, or dentist of any drug which under federal or Ohio law can be sold only on prescription.

(M) The using by any person to his own advantage, or revealing, other than to the director of agriculture or to the courts when relevant in any judicial proceeding under sections 3715.52 to 3715.72 of the Revised Code, any information acquired under authority of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, concerning any information which is a trade secret is entitled to protection;

(N) The issuance by the manufacturer, packer, or distributor of a dangerous drug of any advertisements, catalogues, or price lists, except those lists specifically designed for disseminating price change information, that do not contain in clearly legible form the name and place of busi-

ness of the manufacturer who mixed the final ingredients and if different, the manufacturer who produced the drug in its finished dosage form and, if different, the packer or distributor.

HISTORY: 127 v 819 (Eff 9-13-57); 129 v 582 (799) (Eff 1-10-61); 137 v S 45. Eff 1-1-78.

The effective date of S 45 is set by section 3 of the act.

#### *Cross-References to Related Sections*

Penalty, RC § 3715.99(D).

Applicability of RC §§ 3715.52 to 3715.71 to the sale of shell eggs when not in conflict with RC §§ 925.02 to 925.07.1, RC §§ 925.02.

Pharmacists; disciplinary action by state board of pharmacy for willful violation of RC §§ 3715.52 to 3715.72, RC § 4729.16.

See RC §§ 3715.01, 3715.52, 3715.54-3715.57, 3715.59, 3715.60, 3715.63-3715.71 which refer to RC §§ 2715.52 to 3715.72.

See RC §§ 3715.01, 3715.53, 3715.54, 3715.99 which refer to this section.

#### *Ohio Administrative Code*

Display of placard. OAC 901:3-23-02.

#### *Comparative Legislation*

Adulteration of food:

- Cal.—Health & Safety Code §§ 26520 et seq
- Fla.—Stat. Ann. § 500.10
- Ill.—Ann. Stat. ch. 56½, § 506
- Ind.—Code § 16-1-29-2 et seq
- Ky.—Rev. Stat. Ann. § 217.025

Mich.—Comp. Laws Ann. § 289.716

N.Y.—Agric. & Mkts. Law § 198 et seq

Pa.—Stat. Ann. tit. 31, § 1 et seq

#### *Misbranding food and drugs:*

Cal.—Health & Safety Code §§ 26550, 26630

Fla.—Stat. Ann. §§ 500.11, 500.15

Ill.—Ann. Stat. ch. 56½, § 506

Ind.—Code § 16-1-29-7 et seq, 16-1-30-5 et seq

Ky.—Rev. Stat. Ann. § 217.035 and 217.065

Mich.—Comp. Laws Ann. § 289.717

N.Y.—Agric. & Mkts. Law § 201

Pa.—Stat. Ann. tit. 31, § 1 et seq

#### *Research Aids*

##### *Adulteration and misbranding:*

O-Jur2d: Drugs §§ 11, 14; Food §§ 10, 14; Wts & M § 20

Am-Jur2d: Food § 21-26

##### *Civil liability; practice and procedure:*

O-Jur2d: Food §§ 52, 57

Am-Jur8d: Food §§ 84 et seq

##### *Criminal liability; practice and procedure:*

O-Jur2d: Food § 43

Am-Jur2d: Food § 74 et seq

#### *ALR*

Adulterated: construction and application of Federal Food, Drug, and Cosmetic Act § 402(a)(3) as to food deemed "adulterated," if it is filthy or the like, or unfit for food. 45 ALR2d 861.

*Law Review*

Advertising of food and drugs: concealing a truth, hinting a lie. Comment: Barry S. Donner. 8 Akron LRev 456 (1975).

Consumer protection in Ohio against false advertising and deceptive practices. James W. Carpenter, 32 OSLJ 1 (1971).

Products liability—the test of consumer expectation for “natural” defects in food products. Note. Charles Robert Janes. 37 OSLJ 634 (1976).

Reasonable certainty of no harm: reviving the safety standard for food additives, color additives, and animal drugs. Daryl M. Freedman, 7 EcologyLQ 245 (1978) .

The product liability of manufacturers: an understanding and exploration. Donald M. Jenkins. 4 AkronLRev 135 (1971).

Unwanted pregnancy and the pill—the question of liability of the manufacturer. Note. James M. Bordicks. 41 CinLRev 335 (1972).

No. 85-619

3

Supreme Court, U.S.

FILED

NOV 21 1985

JOSEPH F. SPANIOLO,  
CLERK

IN THE  
**SUPREME COURT OF THE UNITED STATES**

OCTOBER TERM, 1985

MERRELL DOW PHARMACEUTICALS, INC.,  
Petitioner,

vs.

LARRY JAMES CHRISTOPHER THOMPSON AND  
DONNA LYNN THOMPSON AS NEXT FRIENDS AND  
GUARDIANS OF JESSICA ELIZABETH THOMPSON,  
LARRY JAMES CHRISTOPHER THOMPSON,  
INDIVIDUALLY AND DONNA LYNN THOMPSON  
INDIVIDUALLY, et al.,  
Respondents.

On Writ of Certiorari to the  
United States Court Of Appeals for the  
Sixth Circuit

REPLY BRIEF FOR PETITIONER

Frank C. Woodside III  
2100 Fountain Square Plaza  
511 Walnut Street  
Cincinnati, Ohio 45202  
(513) 977-8200

Counsel for Petitioner

Of Counsel:

John E. Schlosser  
Christine L. McBroom  
Kerry C. Green  
DINSMORE & SHOHL  
2100 Fountain Square Plaza  
511 Walnut, Street  
Cincinnati, Ohio 45202

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## IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1985

No. 85-619

MERRELL DOW PHARMACEUTICALS, INC.,  
Petitioner,

vs.

LARRY JAMES CHRISTOPHER THOMPSON AND  
DONNA LYNN THOMPSON AS NEXT FRIENDS AND  
GUARDIANS OF JESSICA ELIZABETH THOMPSON,  
LARRY JAMES CHRISTOPHER THOMPSON,  
INDIVIDUALLY AND DONNA LYNN THOMPSON  
INDIVIDUALLY, et al.,  
Respondents.

On Writ of Certiorari to the  
United States Court Of Appeals for the  
Sixth Circuit

REPLY BRIEF FOR PETITIONER

### INTRODUCTION

The district court recognized that the fourth cause of action in each of the respondents' complaints featured, as an indispensable element, alleged violations by petitioner of the Federal Food, Drug and Cosmetic Act. Because the fourth cause of action in each case "necessarily depends" upon the resolution of a substantial question of federal law, each such

cause of action (and each such lawsuit) is one "arising under" federal law and within the original jurisdiction of the district court.

Petitioner has never disputed that *other* causes of action contained in the respondents' complaints, including the non-federal negligence claims, were not dependent on any issue of federal law. However, this did not deprive the district court of jurisdiction, since it was bound to analyze the respondents' causes of action *separately* to determine whether a federal issue was a necessary element of *any* of them. This is the fashion in which this Court in *Franchise Tax Bd. v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983) analyzed the two causes of action in that suit to determine whether *either* was necessarily dependent on a federal issue for the plaintiffs' recovery.

Respondents have not addressed the arguments set forth in the petition and thus tacitly concede that federal jurisdiction does not require that all of their causes of action involve an indispensable federal issue. Now, for the first time, respondents argue that even their fourth causes of action were not dependent on the Federal Food, Drug and Cosmetic Act violations which they alleged. Though respondents never so positioned themselves before, respondents now allege that petitioner violated the Ohio Pure Food and Drug Act and that this provides an alternate ground (based purely on state law) for possible recovery under the fourth causes of action. Because respondents have raised this new issue, petitioner is filing this reply brief.

## ARGUMENT

### POINT I

**THE OHIO PURE FOOD AND DRUG ACT WAS NOT RAISED BELOW AND, IN ANY EVENT, HAS NO APPLICATION TO DRUGS MANUFACTURED, DISTRIBUTED, AND PRESCRIBED IN FOREIGN COUNTRIES, INGESTED BY FOREIGN CITIZENS, AND REGULATED BY FOREIGN GOVERNMENTS.**

#### A. Respondents Failed to Raise Application Of The Ohio Pure Food And Drug Act In The Courts Below.

Respondents state that their respective fourth causes of action allege not only violation of the Federal Food, Drug and Cosmetic Act, "but also the Ohio Pure Food and Drug Law as well." Respondents' brief at 10. The Ohio Pure Food and Drug Act, Ohio Rev. Code Ann. §§ 3715.01, *et seq.* (Page 1980), has nothing to do with their claims. Whether the Federal Food, Drug and Cosmetic Act pertains is the issue raised in their respective fourth causes of action.

Respondents' complaints do not include allegations of violations of the Ohio Pure Food and Drug Act. Petition at 16a-17a and 26a-27a. Respondents' complaints do not even mention Ohio law. *Id.* It was not until respondents' motion to remand that any mention was made of Ohio law, *i.e.*, the alleged effect under Ohio law of the claimed federal law violations. Respondents' brief at 4a. "Under Ohio law, violation of a safety statute is negligence *per se*, rendering the actor liable to plaintiff if his negligence caused or contributed to causing the plaintiff's injury. Plaintiffs will amend their complaint to include this allegation." *Id.* This amendment was never attempted.

Regardless of the assertion set forth by respondents in their motion to remand, the district court was limited in its determination of the existence of jurisdiction upon removal to the allegations contained in the complaints. The indication that a

suit is one arising under the laws of the United States must be found exclusively in a plaintiff's statement of his own cause of action, unaided by anticipated defenses to those allegations contained in the complaint. *Louisville and Nashville R.R. Co. v. Mottley*, 211 U.S. 149 (1908); *Taylor v. Anderson*, 234 U.S. 74 (1914); *Smith v. Kansas City Title Co.*, 225 U.S. 180 (1921). This concept, known as the well-pleaded complaint rule, was reiterated in *Franchise Tax Bd. v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983).

A federal court must determine whether the true nature of the claim is federal, regardless of a plaintiff's characterization. *Federated Department Stores v. Moitie*, 452 U.S. 394, 397 n.2 (1981). Respondents alleged in their fourth causes of action that petitioner violated the Federal Food, Drug and Cosmetic Act and that each respondent family was entitled to \$20,000,000.00 (Twenty Million Dollars) therefor. Petition at 18a and 27a. The district court was correct in holding that under the well-pleaded complaint rule, respondents "right to relief depends upon the . . . application of the . . . laws of the United States." Petition at 7a. The appellate court erred in ignoring the indispensable federal element of each respondent's fourth cause of action.

**B. Even If The Ohio Law Would Have Been Raised, It Would Not Have Applied To These Cases.**

As noted in the petition, any products ingested by respondents were not those of petitioner but were products manufactured and sold by foreign corporations outside the United States. Petition at 3. Respondents attempt, both in their complaints (petition at 13a and 23a), and in their brief, to disguise the true identity of the products which they allegedly ingested.

Mrs. MacTavish (if she took any drug) took "Debendox," a drug made and sold by British corporations in the United Kingdom. Respondents' brief at 3a. Mrs. Thompson (if she took any drug) took a drug made and sold by Canadian corporations in Canada. Debendox and Canadian Bendectin are

made, sold and prescribed under the regulations of the governments of these two foreign countries. Neither of the respondent mothers took a drug manufactured or sold by petitioner in the United States.

Thus, Ohio law would not apply to these actions. Ohio conflict of law principles dictate that the laws of the United Kingdom and Canada will eventually be applied to these claims. Ohio has adopted the conflicts theory stated in 1 Restatement of the Law 2d, *Conflicts of Laws* (1971), *i.e.*, a presumption that the law of the place of injury controls unless another jurisdiction has more significant relationship to the lawsuit. *Morgan v. Biro Manufacturing Co.*, 15 Ohio St. 3d 339, 474 N.E.2d 286 (1984). The alleged injuries in these cases occurred in the United Kingdom and Canada, where the drugs were manufactured, sold, prescribed and allegedly ingested and where the children were born. Obviously, the United Kingdom and Canada have a more significant relationship to the lawsuit than does the state of Ohio and thus an Ohio court would apply those countries' laws. See *In re Richardson-Merrell, Inc.*, 545 F. Supp. 1130 (S.D. Ohio) *aff'd. sub nom. Dowling v. Richardson-Merrell Inc.*, 727 F.2d 608 (6th Cir. 1984); *Richard D. Chambers v. Merrell Dow Pharmaceuticals Inc.*, Case Nos. A-84-7926, et al. (Ct. Comm. Pleas Hamilton Co., Ohio Nov. 13, 1985) (both holding that in claims of United Kingdom Debendox plaintiffs, United Kingdom law would apply); *Vandervliet v. Richardson-Merrell, Inc.*, Case No. C-1-82-470 (S.D. Ohio Apr. 13, 1984) (holding that in claims of Canadian Bendectin plaintiffs, Canadian law would apply).

Moreover, the Ohio Pure Food and Drug Act, Ohio Rev. Code Ann. §§ 3715.01 *et seq.* (Page 1980), would not apply to the drugs ingested by respondents in Scotland and Canada. The Ohio statute applies only to drugs for which a new drug application has become effective under its provisions or the provisions of the Federal Food, Drug and Cosmetic Act. Ohio Rev. Code Ann. § 3715.65 (Page 1980). Although it is petitioner's position that the Federal Food, Drug and Cosmetic

Act would likewise not apply to foreign-made drugs, respondents *alleged* that this statute applies, thus creating the federal question giving rise to federal jurisdiction.

## POINT II

### FEDERAL QUESTION JURISDICTION EXISTS BECAUSE RESPONDENTS ALLEGED, *INTER ALIA*, A RIGHT OF ACTION UNDER THE FEDERAL FOOD, DRUG AND COSMETIC ACT.

Respondents devote most of their brief to argument and citation that no private right of action, created by the Federal Food, Drug and Cosmetic Act or implied thereunder, exists in these cases and therefore, no federal question jurisdiction is present. Respondents have missed the entire thrust of petitioner's argument. Whether or not the alleged violations of the Federal Food, Drug and Cosmetic Act afford respondents a right to relief is not the pertinent issue before this Court, nor was it the pertinent issue before the courts below.

Petitioner agrees that no private right of action exists under the Federal Food, Drug and Cosmetic Act. However, the issue presented to the district court in these cases was whether respondents *alleged*, in their complaints, that they were entitled to relief for violation of that federal statute. In each fourth cause of action, respondents alleged "[t]hat the defendants' violation of said Federal Statutes directly and proximately caused the injuries suffered by said Minor. . . ." Petition at 18a and 27a. Respondents also alleged that this violation gave rise to a rebuttable presumption of negligence. *Id.* Thus, they alleged that the violation (1) gave rise to a private right of action and (2) gave rise to a rebuttable presumption. The courts below did not consider the first of these two issues. A determination of the private right of action issue was, and is, not necessary to resolve the questions before this Court.

Respondents are confusing the question of whether a court has jurisdiction, with the question whether the allegations state claims for relief upon which relief can be granted.

Jurisdiction, therefore, is not defeated as respondents seem to contend, by the possibility that the averments might fail to state a cause of action on which petitioners could actually recover. *For it is well settled that the failure to state a proper cause of action calls for a judgment on the merits and not for a dismissal for want of jurisdiction.* Whether a complaint states a cause of action on which relief could be granted is a question of law and just as issues of fact must be decided after and not before the court has assumed jurisdiction over the controversy. If the court does later exercise its jurisdiction to determine that the allegations in the complaint do not state a ground for relief, then dismissal of the case would be on the merits, not for want of jurisdiction.

*Fogel v. Chestnutt*, 668 F.2d 100, 105 (2d Cir.) *cert. denied*, 459 U.S. 828 (1981) (emphasis added). *See also Mt. Healthy City Bd. of Education v. Doyle*, 429 U.S. 273 (1976).

The district court would have been obliged, had the cases not been dismissed on *forum non conveniens* grounds, to construe, or interpret the statute so as to determine respondents' right to relief. Respondents' respective fourth causes of action alleged the Federal Food, Drug and Cosmetic Act violations, and necessarily depended upon a resolution of disputed questions about that federal statute. The district court had jurisdiction because, under *Franchise*, respondents' claims arose under federal law whether or not a right to relief exists.

**CONCLUSION**

For the reasons stated in this reply brief and in the petition, the judgment of the appellate court should be reversed and the case should be remanded to the United States Court of Appeals for the Sixth Circuit with directions to affirm the judgment appealed from. In the alternative, this Court should grant certiorari to review the decision of the appellate court after further briefing by the parties.

Dated: November 20, 1985.

Respectfully submitted,

Frank C. Woodside III  
2100 Fountain Square Plaza  
511 Walnut Street  
Cincinnati, Ohio 45202  
(513) 977-8200

Counsel for Petitioner

Of Counsel:

John E. Schlosser  
Christine L. McBroom  
Kerry C. Green  
DINSMORE & SHOHL  
2100 Fountain Square Plaza  
511 Walnut, Street  
Cincinnati, Ohio 45202

OCT 16 1985

JOSEPH F. SPANIOLO, JR.  
CLERK

14  
No. 85-619

IN THE  
**SUPREME COURT OF THE UNITED STATES**

OCTOBER TERM, 1985

MERRELL DCW PHARMACEUTICALS, INC.,  
Petitioner,

vs.

LARRY JAMES CHRISTOPHER THOMPSON AND  
DONNA LYNN THOMPSON AS NEXT FRIENDS AND  
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LARRY JAMES CHRISTOPHER THOMPSON,  
INDIVIDUALLY AND DONNA LYNN THOMPSON,  
INDIVIDUALLY, *et al.*,

Respondents.

On Writ of Certiorari to the  
United States Court of Appeals for the  
Sixth Circuit

JOINT APPENDIX

STANLEY M. CHESLEY  
[Counsel of Record]  
1513 Central Trust Tower  
Fourth and Vine Streets  
Cincinnati, Ohio 45202  
(513) 621-0267

Counsel for Respondents

FRANK C. WOODSIDE III  
[Counsel of Record]  
2100 Fountain Square Plaza  
511 Walnut Street  
Cincinnati, Ohio 45202  
(513) 977-8200

Counsel for Petitioner

Petition for Certiorari filed October 11, 1985  
Certiorari Granted December 2, 1985

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**RELEVANT DOCKET ENTRIES**

**UNITED STATES COURT OF APPEALS  
FOR THE SIXTH CIRCUIT**

Case No. 84-3418

Appeal from the Southern District of Ohio,  
Western Division, at Cincinnati

**LARRY JAMES CHRISTOPHER THOMPSON and  
DONNA LYNN THOMPSON, as guardians of  
Jessica Elizabeth Thompson, a minor;  
LARRY JAMES CHRISTOPHER THOMPSON and  
DONNA LYNN THOMPSON, Individually;  
NEIL FRAZER MacTAVISH and  
MARGARET MacTAVISH as guardians of Neil MacTavish;  
NEIL FRAZER MacTAVISH and  
MARGARET MacTAVISH, Individually,  
Plaintiffs-Appellants,  
vs.  
MERRELL DOW PHARMACEUTICALS, INC., fka  
RICHARDSON MERRELL, INC.,  
Defendants-Appellees.**

Date  
1984

06/01 Copy Notice of Appeal, filed; and cause docketed.

06/06 Certified Record, (2 vol. of pleadings)

Date  
1984

06/26 Notice from court reporter, Kuppin, transcript unnecessary for appeal purposes.

08/09 Certified Supplemental Record, (1 vol. of pleadings)

11/20 Brief (10) of appellant (m-11/20)

12/20 Brief (10) of appellee (m-12/20)

Date  
1985

01/07 REPLY BRIEF (10) Appellant (m-01/07)

01/10 JOINT APPENDIX (5) (Vols. I, II, III) [84-3366/3418/39/95/3796]

01/14 CERTIFIED SUPPLEMENTAL RECORD (01 vol. pleadings), filed [84-3366/3418/39/95/3796]

02/01 MOTION appellee to file supplement to joint appendix and correct index pages in original appendix (m-02/01) [84-3366/3418 3439/3495/3796] (Motion Granted, JPH/kmp, per jst, 2/5)

02/01 SUPPLEMENTAL JOINT APPENDIX (5) (m-02-01) and filed 2/5

03/07 ADDITIONAL CITATIONS by appellant (m-03/05)

03/15 ADDITIONAL CITATIONS by appellee (Woodside) (m-03/14)

07/15 JUDGMENT of the District Court is reversed and the case is remanded with instructions, appellants to recover costs from appellee (Jones, Krupansky and Hull, JJ.)

Date  
1985

07/15 OPINION by Jones, J.

10/21 NOTICE of filing petition for certiorari (S. Ct. No. 85-619) 10/11/85

## RELEVANT DOCKET ENTRIES

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO, WESTERN DIVISION

83-1436 Thompson v. MDL

## Date

09-08-83 PETITION FOR REMOVAL from Hamilton Co.  
Cthse — attached are the following COM-  
PLAINT, JURY DEMAND

\* \* \*

10-14-83 MOTION TO REMAND UNDER § 1447(c) for  
Lack of Juris, by pltf.

10-31-83 MEMO IN OPP (979), by deft.

11-22-83 REPLY IN SUPPORT (979), by pltf.

12-21-83 MOTION TO DISMISS ON GROUNDS OF  
FORUM NON CONVENIENS, BY DEFT.

\* \* \*

01-24-84 MEMO OPP (1132), by pltf.

02-08-84 REPLY IN SUPPORT (1132), by deft.

\* \* \*

05-14-84 ORDER DENYING PLTF'S Motion to remand  
(979) and GRANTING deft's motion to dismiss on  
*forum non conveniens* (1132) CMTc LC/WOOD-  
SIDE

05-14-84 JUDGMENT ENTRY ON DECISION OF  
COURT (1676) JS-6 submitted

05-18-84 ACCEPTANCE OF CONDITIONS OF ORDER  
OF JUDGMENT OF DISMISSAL by deft.

05-22-84 NOTICE OF APPEAL by pltf from judgment of  
5-14-84.

05-30-84 Sent Pleadings #1677-1711-1718 to COFA.  
(Copies) & 1676 (m)

06-04-84 Acknowledge Receipt from COFA Their No.  
84-3418 (m)

## RELEVANT DOCKET ENTRIES

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO, WESTERN DIVISION

83-1437 MacTavish v. MDL

## Date

09-08-83 PETITION FOR REMOVAL by deft. — Attached  
are complaint & Jury demand

\* \* \*

10-31-83 MEMO IN OPP (979), by deft.

11-22-83 REPLY IN SUPPORT (979), by pltf.

12-21-83 MOTION TO DISMISS ON GROUNDS OF  
FORUM NON CONVENIENS, by deft.

\* \* \*

01-24-84 MEMO OPP (1133), by pltf.

02-08-84 REPLY IN SUPPORT (1133), by deft

\* \* \*

05-14-84 ORDER DENYING PLTF'S motion to remand  
(979) and GRANTING deft's Motion to Dismiss on  
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05-22-84 NOTICE OF APPEAL by pltf from judgment of  
5-14-84

05-30-84 Sent Pleadings #1678-1712-1718 to COFA. (copies)  
(m)

UNITED STATE COURT OF APPEALS  
FOR THE SIXTH CIRCUIT

No. 84-3418

LARRY JAMES CHRISTOPHER THOMPSON, et al.,  
Plaintiffs-Appellants,

v.

MERRELL DOW PHARMACEUTICALS, INC., f/k/a  
Richardson Merrell, Inc.,  
Defendant-Appellee.

Before: JONES and KRUPANSKY, Circuit Judges; and  
HULL, Chief District Judge.

**JUDGMENT**

[Filed July 15, 1985]

ON APPEAL from the United States District Court for the  
Southern District of Ohio.

THIS CAUSE came on to be heard on the record from the  
said District Court and was argued by counsel.

ON CONSIDERATION WHEREOF, It is now here  
ordered and adjudged by this court that the judgment of the  
said District Court in this case be and the same is hereby  
reversed and the case is remanded with instructions consistent  
with this opinion.

It is further ordered that Plaintiffs-Appellants recover from  
Defendant-Appellee the costs on appeal, as itemized below,  
and that execution therefor issue out of said District Court, if  
necessary.

ENTERED BY ORDER OF THE  
COURT

John P. Hehman, Clerk

/s/ JOHN P. HEHMAN,  
Clerk

ISSUED AS AMENDED MANDATE: August 15, 1985  
COSTS: Awarded to appellant)

Filing fee .....\$ 70.00  
Printing .....\$332.50  
Total .....\$402.50

A True Copy.

Attest:

/s/ GARY McCARTHY  
Deputy Clerk

No. 84-3418

UNITED STATES COURT OF APPEALS  
FOR THE SIXTH CIRCUITLARRY JAMES CHRISTOPHER THOMP-  
SON, et al.,*Plaintiffs-Appellants,*

v.

MERRELL DOW PHARMACEUTICALS,  
INC.,*Defendant-Appellee.*ON APPEAL from the  
United States District  
Court for the South-  
ern District of Ohio.

Decided and Filed July 15, 1985

Before: JONES and KRUPANSKY,<sup>\*</sup> Circuit Judges; and HULL,  
Chief District Judge.\*

JONES, Circuit Judge. This appeal presents the issue of whether actions filed in state court are properly removable to federal court if the complaints allege in part that the defendant violated the Food, Drug and Cosmetic Act and that this violation constituted "a rebuttable presumption of negligence." Plaintiffs-appellants contend that these cases presented no federal question upon which removal could be properly based. We agree and reverse and remand.

Plaintiffs-appellants, the Thompsons and the MacTavishes, are residents of Scotland and Canada respectively. They filed their complaints against defendant-appellee, Merrell Dow Pharmaceuticals, Inc., in the Court of Common Pleas, Hamilton County, Ohio. The complaints alleged that Mrs. Thompson and Mrs. MacTavish ingested Benedectin, a drug developed, produced, manufactured, and sold by Merrell

\* Honorable Thomas G. Hull, District Judge, United States District Court for the Eastern District of Tennessee, sitting by designation.

Dow, and that the ingestion of the drug resulted in the birth defects suffered by both Jessica Thompson and Neil MacTavish. Each complaint alleged liability based upon the state-created theories of common law fraud, negligence, strict liability, and breach of warranty. They also alleged that Merrell Dow violated certain provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-392 (FDCA) and that those violations establish a rebuttable presumption of negligence. Pursuant to 28 U.S.C. § 1441, Merrell Dow removed these actions to the district court where they were consolidated. Plaintiffs filed a motion to remand under § 1447(c) for lack of subject matter jurisdiction. The district court denied plaintiffs' motion to remand and granted Merrell Dow's motion to dismiss on the ground of forum non conveniens. Appellants then filed this appeal.

Removal jurisdiction in a federal district court is premised upon 28 U.S.C. § 1441. Section 1441(a) provides for removal of actions generally, and § 1441(b) limits a defendant's ability to remove actions from a state court to situations where the defendant is not a citizen of the state in which such action is brought. Section 1441(c) permits a district court to determine all issues raised in an action when one claim, which would be removable if sued upon alone, is joined with one or more otherwise non-removable claims. The standard for determining when an action is removable is whether the court would have had jurisdiction, subject to the limitations of § 1441(b), if the action had been instituted originally in federal court under 28 U.S.A. § 1331 or § 1332. See *Franchise Tax Board v. Construction Laborers Vacation Trust*, 103 S. Ct. 2841, 2845 (1983). Consequently, a case removed to federal court under the guise of federal question jurisdiction presents a federal question when it "arises under" federal law. In *Franchise Tax Board*, the Court stated:

Under our interpretations, Congress has given the lower courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a well pleaded complaint establishes either that federal law creates the

cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law.

*Id.* at 2856.

The parties agree that the FDCA does not create or imply a private right of action for individuals injured as a result of violations of the Act. Federal question jurisdiction would, thus, exist only if plaintiffs' right to relief *depended necessarily* on a substantial question of federal law. Plaintiffs' causes of action referred to the FDCA merely as one available criterion for determining whether Merrell Dow was negligent. Because the jury could find negligence on the part of Merrell Dow without finding a violation of the FDCA, the plaintiffs' causes of action did not depend necessarily upon a question of federal law. Consequently, the causes of action did not arise under federal law and, therefore, were improperly removed to federal court. See *Zeig v. Shearson/American Express, Inc.*, 592 F. Supp. 612, 613-14 (E.D. Va. 1984); *State of Florida ex rel. Broward County*, 329 F. Supp. 364, 366 n.3 (S.D. Fla. 1971).

Accordingly, the judgment of the district court is REVERSED and the case is REMANDED with instructions to remand the cases to the Court of Common Pleas for Hamilton County, Ohio, where they were first filed.

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO-WESTERN DIVISION

C-1-83-1436

LARRY JAMES CHRISTOPHER THOMPSON, et al.,  
v.  
MERRELL DOW PHARMACEUTICALS, INC.

Chief Judge Carl B. Rubin

Judgment  
(Filed May 14, 1984)

\* \* \*

Decision by Court. This action came to trial or hearing before the Court with the judge (magistrate) named above presiding. The issues have been tried or heard and a decision has been rendered.

IT IS ORDERED AND ADJUDGED  
that plaintiff's Motion to Remand (Doc. No. 979) is hereby DENIED and defendant's Motion to Dismiss on *forum non conveniens* grounds (1132) is hereby GRANTED.

Clerk

KENNETH J. MURPHY

(By) Deputy Clerk

/s/ STEPHEN M. SNYDER

Date 5-14-84

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO-WESTERN DIVISION

\_\_\_\_\_  
C-1-83-1437  
\_\_\_\_\_

NEIL FRAZER MACTAVISH, et al.,  
v.  
MERRELL DOW PHARMACEUTICALS, INC.

\_\_\_\_\_  
Chief Judge Carl B. Rubin  
\_\_\_\_\_

**Judgment**  
(Filed May 14, 1984)

\* \* \*

Decision by Court. This action came to trial or hearing before the Court with the judge (magistrate) named above presiding. The issues have been tried or heard and a decision has been rendered.

**IT IS ORDERED AND ADJUDGED**

. . . that plaintiff's Motion to Remand (Doc. No. 979) is hereby DENIED and defendant's Motion to Dismiss on *forum non conveniens* grounds (1133) is hereby GRANTED.

Clerk

KENNETH J. MURPHY

(By) Deputy Clerk

/s/ STEPHEN M. SNYDER

Date 5-14-84

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

\_\_\_\_\_  
MDL #486  
\_\_\_\_\_

IN RE: RICHARDSON-MERRELL, INC.  
"BENEDICTIN" PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATED TO:

THOMPSON	C-1-83-1436
MacTAVISH	C-1-83-1437

**ORDER DENYING PLAINTIFFS'  
MOTION TO REMAND (Doc. No. 979)  
AND GRANTING DEFENDANT'S  
MOTIONS TO DISMISS ON  
FORUM NON CONVENIENS GROUNDS**  
(Doc. Nos. 1132, Thompson; 1133, MacTavish)  
(Filed May 14, 1984)

This matter is before the Court on plaintiffs' Motion (Doc. No. 979) to remand the above-captioned cases to the Court of Common Pleas, Hamilton County, Ohio, and on defendant's Motions (Doc. Nos. 1132 and 1133) to dismiss on *forum non conveniens* grounds. For the reasons which follow, plaintiffs' Motion will be denied and defendant's Motions will be granted.

**I. Motion to Remand**

These cases were originally filed in the Court of Common Pleas, Hamilton County, Ohio, and removed by defendants to this Court pursuant to 28 U.S.C. § 1441. Removal was

premised on this Court's jurisdiction over cases "arising under the Constitution, treaties or laws of the United States." See 28 U.S.C. § 1441(b). See also 28 U.S.C. §§ 1441(a), 1331.<sup>1</sup> Plaintiffs subsequently filed their Motion to Remand, asserting that federal-question jurisdiction was lacking and that the case had been improvidently removed from state court.<sup>2</sup>

Specifically at issue is the fourth cause of action in each Complaint. That cause of action, used by defendant as the basis for removal, alleges negligence resulting from defendant's alleged failure to comply with the labeling provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("the Act"). After outlining pertinent provisions of the Act in Paragraphs 18 through 24 of each Complaint, plaintiffs set forth the following in Paragraphs 25 through 27:

25. That the promotion of said drug, Benedectin, by the defendant . . . constituted misbranding of said pharmaceutical drug per sub-sections (a), (f)(2) and (j) of § 502 and (u) of § 201 of [the Act].

26. That violation of said Federal Statutes in the promotion of said drug, Benedectin, by the Defendant herein enumerated, constitutes a rebuttable presumption of negligence.

27. That the Defendant's violation of said Federal Statutes directly and proximately caused the injuries suffered by [plaintiffs] . . .

The question facing the Court is whether plaintiffs' fourth cause of action states a claim "arising under" the laws of the United States.

In attempting to clarify the phrase "arising under," the Supreme Court has formulated definitions employing varying

<sup>1</sup> Section 1441(c) provides for the removal of an entire case if it contains at least one "separate and independent claim or cause of action, which would be removable if sued upon alone." The district court may, in its discretion, determine all the issues in the case or remand those not within its original jurisdiction.

<sup>2</sup> The parties agree that federal-question jurisdiction provides the only arguable basis for removal of these cases.

language. See, e.g., *Gully v. First National Bank*, 299 U.S. 109 (1936); *Moore v. Chesapeake & Ohio Ry.*, 291 U.S. 205 (1934); *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921); *American Well Works Co. v. Layne & Bowler Co.*, 241 U.S. 257 (1916).

Upon examination of the pertinent cases, this Court concludes that the definition set forth in *Smith*, *supra*, provides the appropriate standard for analysis. Cf., *T.B. Harms Co. v. Eliscu*, 339 F.2d 823, 827 (2nd Cir. 1964), *cert. denied*, 381 U.S. 915 (1965) (*Smith* was "path-breaking" opinion). See also *Franchise Tax Bd. v. Construction Laborers Vacation Trust*, \_\_\_ U.S. \_\_\_, 103 S.Ct. 2841, 2846 (1983).

In *Smith*, the Supreme Court stated the "general rule" as follows:

[W]here it appears from the bill or statement of the plaintiff that the right to relief depends upon the construction or application of the Constitution or laws of the United States, and that such federal claim is not merely colorable, and rests upon a reasonable foundation, the District Court has jurisdiction. . . .

*Smith*, *supra*, at 199.<sup>3</sup>

Applying the rule as stated in *Smith*, the Court concludes that federal-question jurisdiction exists over these cases and that they were properly removed. Although plaintiffs' fourth cause of action is technically a claim for negligence pursuant to state law, the sole basis for the claim is the alleged violation of the federal Act by defendant. Therefore, the key issue with respect to that cause of action is whether defendant's conduct violated the Act. Phrased in terms of the *Smith* standard, plaintiffs' "right to relief depends upon the . . . ap-

<sup>3</sup> This Court recognizes that *Smith* is in apparent conflict with *Moore*, *supra*, and that the conflict appears, at first blush, to be irreconcilable. See, M. Redish, *Federal Jurisdiction*, 67 (1980). However, subsequent federal court decisions have reconciled and distinguished the two cases on the basis of the state statutory schemes involved in each. See *Abrams v. Citibank*, 537 F.Supp. 1192, 1196 (S.D. N.Y. 1982). The case at bar is analagous to *Smith* and therefore distinguishable from *Moore*.

plication of the . . . laws of the United States." *Smith, supra*, at 199. Accordingly, the Court holds that plaintiffs' fourth cause of action arises under the laws of the United States and that these cases were properly removed to federal court.<sup>4</sup> Plaintiff's Motion to Remand will be denied.

## II. Motions to Dismiss

The precise issues raised by defendant's Motions to Dismiss on *forum non conveniens* grounds have previously been considered by the Court under factual circumstances virtually identical with those at bar. See *order Granting Defendant's Motion to Dismiss in Vandervliet* (Doc. No. 1578) (facts virtually identical to *Thompson*); *In Re Richardson-Merrell, Inc.*, 545 F.Supp. 1130 (S.D. Ohio 1983), *aff'd. sub nom Dowling v. Richardson-Merrell, Inc.*, 727 F.2d 608 (6th Cir. 1984) (facts identical to *MacTavish*). Defendant's Motion with respect to *Thompson* will be granted for the reasons set forth in *Vandervliet, supra*, and defendant's Motion with respect to *MacTavish* will be granted for the reasons set forth in *In Re Richardson-Merrell, Inc., supra*. The granting of each of defendant's motions is subject to the five conditions set forth in *Dowling, supra*, at 611, 616.

Accordingly, for the reasons set forth above, and subject to the conditions noted, plaintiffs' Motion to Remand (Doc. No. 979) is hereby DENIED and defendant's Motions to Dismiss on *forum non conveniens* grounds (Doc. Nos. 1132 and 1133) are hereby GRANTED.

IT IS SO ORDERED.

/s/ CARL B. RUBIN, Chief Judge  
United States District Court

<sup>4</sup> In asserting a lack of federal-question jurisdiction, plaintiffs argue, *inter alia*, that jurisdiction is lacking because no private right of action exists under the Act. The Court is not impressed by this argument. This is not a situation where plaintiffs are seeking some form of relief under the Act itself.

## COURT OF COMMON PLEAS HAMILTON COUNTY, OHIO

Case No. A8307058

LARRY JAMES CHRISTOPHER THOMPSON and  
DONNA LYNN THOMPSON as Next Friends and  
Guardians of JESSICA ELIZABETH THOMPSON, A Minor  
222 Church Street  
Napanee, Ontario Canada K7R1C6

LARRY JAMES CHRISTOPHER THOMPSON, Individually  
222 Church Street  
Napanee, Ontario Canada K7R1C6

DONNA LYNN THOMPSON, Individually  
222 Church Street  
Napanee, Ontario Canada K7R1C6

Plaintiffs,

vs.

MERRELL-DOW PHARMACEUTICALS, INC.,  
(formerly known as Richardson-Merrell, Inc.)  
a Delaware Corporation  
2110 East Galbraith Road  
Cincinnati, Ohio 45215

Defendant.

COMPLAINT AND JURY DEMAND  
[Filed September 1, 1983]

Now come the Plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, and Individually, and state their causes of action as follows.

### FIRST CAUSE OF ACTION

1. The Plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson, as Next Best Friends and Guardians of Jessica Elizabeth Thompson, a Minor and Individually, state that they are residents of the City of Ontario, Country of Canada, Providence of Napanee.

2. That Defendant Merrell-Dow Pharmaceutical, Inc., FDBA Merrell-National Laboratories, Division of Richardson-Merrell, Inc., is a Delaware corporation with its principal place of business in the City of Cincinnati, County of Hamilton, State of Ohio.

3. That on or about December of 1978, Plaintiff Donna Lynn Thompson became pregnant with Jessica Elizabeth Thompson.

4. That during the first trimester of said pregnancy, Donna Lynn Thompson began to experience nausea for which her obstetrician prescribed the drug product known as Bendectin.

5. That said product, Bendectin, is a prescription drug made and distributed by the Defendant.

6. That Jessica Elizabeth Thompson was born September 21, 1979 subsequent to which it became obvious that the minor suffered from multiple deformities, including but not limited to, recto-vulvar fistula, anal atresia and sacral agenesis.

7. That as a result of said abnormalities, Jessica Elizabeth Thompson was caused to undergo extensive medical treatment and was and will continue to be required to undergo further medical treatment.

8. That the injuries suffered by Jessica Elizabeth Thompson were directly and proximately caused by the administration of the drug product Bendectin to Donna Lynn Thompson during the first trimester of pregnancy.

9. That the negligence of the Defendant in developing, marketing, producing, manufacturing, distributing and selling a product that Defendant knew or should have known could cause injuries and defects in children such as Jessica Elizabeth Thompson upon ingestion during pregnancy, directly and proximately caused said injuries; that the injuries

were directly and proximately caused by the negligence of the Defendant in failing to test or inadequately testing the potential birth defect producing effects upon ingestion of Bendectin during pregnancy; that injuries were caused, directly and proximately by the negligence of the Defendant in failing to warn the users of Bendectin of the potential birth defect producing effects upon ingestion during pregnancy.

10. That as a direct and proximate result of the aforementioned negligence of the Defendant, Jessica Elizabeth Thompson was and will be caused to suffer considerable pain and suffering and to undergo further medical treatment, and Plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson, as parents of Jessica Elizabeth Thompson, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Larry James Christopher Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff, Donna Lynn Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

### SECOND CAUSE OF ACTION

11. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 10 and for their Second Cause of Action state as follows.

12. That Defendant expressly and impliedly warranted that its product, Bendectin, was of merchantable quality and fit and safe for its intended purposes and uses.

13. That Defendant breached said express and implied warranties of merchantability, fitness and safety and that said breach directly and proximately caused the injuries suffered by Jessica Elizabeth Thompson, a Minor, and that as a direct

and proximate breach of the aforementioned warranties, said Minor was and will be caused to suffer considerable pain and suffering, and to undergo continuous medical treatment, and Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as parents of Jessica Elizabeth Thompson were and will be caused to suffer considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff, Larry James Christopher Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff, Donna Lynn Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

### THIRD CAUSE OF ACTION

14. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 13 and for their Third Cause of Action state as follows.

15. That Defendant is strictly liable in that it developed, marketed, produced, manufactured, distributed and sold an inherently dangerous and defective drug, to-wit Bendectin, which it knew or should have known could cause injuries and defects in children such as said Minor upon ingestion during pregnancy, while failing to test or inadequately testing the potential birth defect producing effects upon ingestion during pregnancy and failing to warn the users of Bendectin of the potential birth defect producing effects upon ingestion during pregnancy.

16. That the foregoing acts and omissions of the Defendant directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment, and Plaintiffs,

Larry James Christopher Thompson and Donna Lynn Thompson, as parents of Jessica Elizabeth Thompson, a Minor, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Larry James Christopher Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Donna Lynn Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

### FOURTH CAUSE OF ACTION

17. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 16 and for their Fourth Cause of Action state as follows.

18. That the applicable Federal law covering the manufacturing and distributing of drugs during the time period in controversy was the Federal Food, Drug and Cosmetics Act passed by the 7th Congress on June 25, 1938, and cited as 52 Stat 1040, as amended.

19. That the purpose of 52 Stat 1040, among other purposes, was to prohibit the movement in Interstate Commerce of misbranded drugs.

20. That per § 201(n) of 52 Stat 1040, the determination as to whether a drug is misbranded includes "not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences, which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary and usual".

21. That Defendant did not at any time during the time period in controversy, reveal or attempt to reveal any facts material to consequences which may result in the unborn offspring of mothers receiving the drug in question for indications relating to pregnancy.

22. That pursuant to § 502(a) of 52 Stat 1040, a drug is deemed misbranded if its labeling is false or misleading in any particular.

23. That pursuant to § 502(f)(2) of 52 Stat 1040, a drug is deemed misbranded unless its labeling bears "such adequate warning against use in those pathologic conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods, or duration of administration or application, in such manner and form, as are necessary for the protection of users".

24. That pursuant to § 502(j) of 52 Stat 1040, a drug is deemed misbranded if it is "dangerous to health when used in the dosage, or with the frequency of duration prescribed, recommended or suggested in the labeling thereof".

25. That the promotion of said drug, Bendectin, by the Defendant for the use in females during the time period in controversy, without revealing or attempting to reveal any facts material to consequences which may result in the unborn offspring of mothers receiving the drug, constituted misbranding of said pharmaceutical drug per sub-sections (a), (f)(2) and (j) of § 502 and (n) of § 201 of 52 Stat 1040.

26. That violation of said Federal Statutes in the promotion of said drug, Bendectin, by the Defendant herein enumerated, constitutes a rebuttable presumption of negligence.

27. That the Defendant's violation of said Federal Statutes directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment, and Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as parents of Jessica Elizabeth Thompson, a Minor, were and will be caused to incur considerable medical

and other expenses and to suffer anxiety and anguish, all to which Plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Larry James Christopher Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Donna Lynn Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

#### FIFTH CAUSE OF ACTION

28. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 27 and for their Fifth Cause of Action state as follows.

29. The Defendant has made false and fraudulent representations of fact as to the safety, nontoxicity, and freedom from side effects of its product Bendectin and those representations were made under circumstances that the said Defendant knew or should have known that they were false, or alternatively, were represented to be true while said Defendant had no knowledge as to the truth thereof and the said Defendant stood to benefit financially by its misrepresentations, active and constructive. These representations were made in promotional literature, product inserts and by detailmen to prescribing physicians. By these representations the Defendant worked a fraud and deceit upon the consuming public, and more particularly, upon the Plaintiffs.

30. The Defendant deliberately pursued a policy of non-disclosure with regard to adverse reactions attributable to the product Bendectin, especially, but not limited to, a number of reporting physicians, each reporting that a number of mothers who used Bendectin during pregnancy gave birth to physically deformed babies. The said Defendant thereby deprived the medical community and the public and the Plaintiffs of significant facts which, if known, would have

permitted an informed judgment of the drug in light of the grave risks attending its use.

31. The Defendant failed to submit all relevant data bearing on the safety of the drug Bendectin to the Food and Drug Administration, as required by law.

32. That the acts and omissions of the Defendant, as aforementioned, directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment; and Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as parents of Jessica Elizabeth Thompson, a Minor, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Larry James Christopher Thompson, Individually, had been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Donna Lynn Thompson, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

#### SIXTH CAUSE OF ACTION

33. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 32 and for their Sixth Cause of Action state as follows.

34. The foregoing acts and omissions of the Defendant were willful, wanton and grossly negligent and caused, directly and proximately, the injuries to Plaintiffs as aforementioned, all to which Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, have been damaged in the amount of Twenty Two Million Five Hundred Thousand (\$22,500,000.00) Dollars

punitive damages; Plaintiff Larry James Christopher Thompson, Individually, has been damaged in the amount of Ten Million (\$10,000,000.00) Dollars punitive damages; and Plaintiff Donna Lynn Thompson, Individually, has been damaged in the amount of Ten Million (\$10,000,000.00) Dollars punitive damages.

WHEREFORE, Plaintiffs Larry James Christopher Thompson and Donna Lynn Thompson, as Next Friends and Guardians of Jessica Elizabeth Thompson, a Minor, demand Judgment against the Defendant in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages and Twenty Two Million Five Hundred Thousand (\$22,500,000.00) Dollars punitive damages; Plaintiff Larry James Christopher Thompson, Individually, demands Judgment against the Defendant in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages and Ten Million (\$10,000,000.00) Dollars punitive damages; and Plaintiff Donna Lynn Thompson, Individually, demands Judgment against the Defendant in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages and Ten Million (\$10,000,000.00) Dollars punitive damages. Plaintiffs also demand all costs, interest and attorneys fees, and all other relief to which they may be entitled.

WAITE, SCHNEIDER, BAYLESS  
& CHESLEY CO., L.P.A.

/s/ Stanley M. Chesley  
1318 Central Trust Tower  
Cincinnati, Ohio 45202  
TRIAL COUNSEL FOR  
PLAINTIFFS

George A. Kokus  
COHEN AND KOKUS  
1521 N.W. 15th Street  
Miami, Florida 33125  
CO-COUNSEL FOR PLAINTIFFS

Allen T. Eaton  
 COHEN AND KOKUS  
 Washington D.C. Office  
 1025 Vermont Avenue, N.W.  
 Suite 503  
 Washington, D.C. 20005  
 CO-COUNSEL FOR PLAINTIFFS

### JURY DEMAND

The Plaintiffs herein demand a trial by jury on all issues.

/s/ Stanley M. Chesley  
 TRIAL COUNSEL FOR  
 PLAINTIFFS.

### COURT OF COMMON PLEAS HAMILTON COUNTY, OHIO.

Case No. A8307057

Neil Frazer MacTavish and Margaret MacTavish as Next  
 Friends and Guardians of Neil MacTavish, A Minor  
 49 Bells Burn Avenue, LinLithgow, Scotland

Neil Frazer MacTavish, Individually  
 49 Bells Burn Avenue, LinLithgow, Scotland

Margaret MacTavish, Individually  
 49 Bells Burn Avenue, LinLithgow, Scotland  
 Plaintiffs,

v.

Merrell-Dow Pharmaceuticals, Inc., (formerly known as  
 Richardson-Merrell, Inc.) a Delaware Corporation  
 2110 East Galbraith Road, Cincinnati, Ohio 45215  
 Defendant.

### COMPLAINT AND JURY DEMAND

[Filed September 1, 1983]

Now come the Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish as Next Friends and Guardians of Neil MacTavish, a Minor, and Individually, and state their causes of action as follows.

### FIRST CAUSE OF ACTION

1. The Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as Next Best Friends and Guardians of Neil MacTavish, a Minor, and Individually, state that they are residents of the City of LinLithgow, Country of Scotland.

2. That Defendant Merrell-Dow Pharmaceuticals, Inc., FDDB Merrell-National Laboratories, Division of Richard-

son-Merrell, Inc., is a Delaware corporation with its principal place of business in the City of Cincinnati, County of Hamilton, State of Ohio.

3. That on or about August of 1978, Plaintiff Margaret MacTavish became pregnant with Neil MacTavish.

4. That during the first trimester of said pregnancy, Margaret MacTavish began to experience nausea for which her obstetrician prescribed the drug product known as Bendectin.

5. That said product, Bendectin, is a prescription drug made and distributed by the Defendant.

6. That Neil MacTavish was born May 11, 1979 subsequent to which it became obvious that the minor suffered from multiple deformities, including but not limited to, complete absence of the right hand; both forearm bones are present, but there are no definite carpals.

7. That as a result of said abnormalities, Neil MacTavish was caused to undergo extensive medical treatment and was and will continue to be required to undergo further medical treatment.

8. That the injuries suffered by Neil MacTavish were directly and proximately caused by the administration of the drug product Bendectin to Margaret MacTavish during the first trimester of pregnancy.

9. That the negligence of the Defendant in developing, marketing, producing, manufacturing, distributing and selling a product that Defendant knew or should have known could cause injuries and defects in children such as Neil MacTavish upon ingestion during pregnancy, directly and proximately caused said injuries; that the injuries were directly and proximately caused by the negligence of the Defendant in failing to test or inadequately testing the potential birth defect producing effects upon ingestion of Bendectin during pregnancy; that injuries were caused, directly and proximately by the negligence of the Defendant in failing to warn the users of Bendectin of the potential birth defect producing effects upon ingestion during pregnancy.

10. That as a direct and proximate result of the

aforementioned negligence of the Defendant, Neil MacTavish was and will be caused to suffer considerable pain and suffering and to undergo further medical treatment, and Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as parents of Neil MacTavish, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Neil Frazer MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff, Margaret MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

## SECOND CAUSE OF ACTION

11. The plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 10 and for their Second Cause of Action state as follows.

12. That Defendant expressly and impliedly warranted that its product, Bendectin, was of merchantable quality and fit and safe for its intended purposes and uses.

13. That Defendant breached said express and implied warranties of merchantability, fitness and safety and that said breach directly and proximately caused the injuries suffered by Neil MacTavish, a Minor, and that as a direct and proximate breach of the aforementioned warranties, said Minor was and will be caused to suffer considerable pain and suffering, and to undergo continuous medical treatment, and Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as parents of Neil MacTavish were and will be caused to suffer considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory

damages; Plaintiff, Neil Frazer MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff, Margaret MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

### THIRD CAUSE OF ACTION

14. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 13 and for their Third Cause of Action state as follows.

15. That Defendant is strictly liable in that it developed, marketed, produced, manufactured, distributed and sold an inherently dangerous and defective drug, to-wit Bendectin, which it knew or should have known could cause injuries and defects in children such as said Minor upon ingestion during pregnancy, while failing to test or inadequately testing the potential birth defect producing effects upon ingestion during pregnancy and failing to warn the users of Bendectin of the potential birth defect producing effects upon ingestion during pregnancy.

16. That the foregoing acts and omissions of the Defendant directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment, and Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as parents of Neil MacTavish, a Minor, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Neil Frazer MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Margaret MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

### FOURTH CAUSE OF ACTION

17. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 16 and for their Fourth Cause of Action state as follows.

18. That the applicable Federal law covering the manufacturing and distributing of drugs during the time period in controversy was the Federal Food, Drug and Cosmetics Act passed by the 7th Congress on June 25, 1938, and cited as 52 Stat 1040, as amended.

19. That the purpose of 52 Stat 1040, among other purposes, was to prohibit the movement in Interstate Commerce of misbranded drugs.

20. That per § 201(n) of 52 Stat 1040, the determination as to whether a drug is misbranded includes "not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences, which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary and usual".

21. That Defendant did not at any time during the time period in controversy, reveal or attempt to reveal any facts material to consequences which may result in the unborn offspring of mothers receiving the drug in question for indications relating to pregnancy.

22. That pursuant to § 502(a) of 52 Stat 1040, a drug is deemed misbranded if its labeling is false or misleading in any particular.

23. That pursuant to § 502(f)(2) of 52 Stat 1040, a drug is deemed misbranded unless its labeling bears "such adequate warning against use in those pathologic conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods, or duration of administration or application, in such manner and form, as are necessary for the protection of users".

24. That pursuant to § 502(j) of 52 Stat 1040, a drug is deemed misbranded if it is "dangerous to health when used in the dosage, or with the frequency of duration prescribed, recommended or suggested in the labeling thereof".

25. That the promotion of said drug, Bendectin, by the Defendant for the use in females during the time period in controversy, without revealing or attempting to reveal any facts material to consequences which may result in the unborn offspring of mothers receiving the drug, constituted misbranding of said pharmaceutical drug per sub-sections (a), (f)(2) and (j) of § 502 and (n) of § 201 of 52 Stat 1040.

26. That violation of said Federal Statutes in the promotion of said drug, Bendectin, by the Defendant herein enumerated, constitutes a rebuttable presumption of negligence.

27. That the Defendant's violation of said Federal Statutes directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment, and Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as parents of Neil MacTavish, a Minor, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages; Plaintiff Neil Frazer MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Margaret MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

#### FIFTH CAUSE OF ACTION

28. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 27 and for their Fifth Cause of Action state as follows.

29. The Defendant has made false and fraudulent representations of fact as to the safety, nontoxicity, and freedom from side effects of its product Bendectin and those representations were made under circumstances that the said Defendant knew or should have known that they were false, or alternatively, were represented to be true while said Defendant had no knowledge as to the truth thereof and the said Defendant stood to benefit financially by its misrepresentations, active and constructive. These representations were made in promotional literature, product inserts and by detailmen to prescribing physicians. By these representations the Defendant worked a fraud and deceit upon the consuming public, and more particularly, upon the Plaintiffs.

30. The Defendant deliberately pursued a policy of non-disclosure with regard to adverse reactions attributable to the product Bendectin, especially, but not limited to, a number of reporting physicians, each reporting that a number of mothers who used Bendectin during pregnancy gave birth to physically deformed babies. The said Defendant thereby deprived the medical community and the public and the Plaintiffs of significant facts which, if known, would have permitted an informed judgment of the drug in light of the grave risks attending its use.

31. The Defendant failed to submit all relevant data bearing on the safety of the drug Bendectin to the Food and Drug Administration, as required by law.

32. That the acts and omissions of the Defendant, as aforementioned, directly and proximately caused the injuries suffered by said Minor and directly and proximately caused and will cause said Minor to suffer considerable pain and suffering and to undergo continuous medical treatment, and Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as parents of Neil MacTavish, a Minor, were and will be caused to incur considerable medical and other expenses and to suffer anxiety and anguish, all to which Plaintiffs, Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Ten Million (\$10,000,000.00) Dollars compen-

satory damages; Plaintiff Neil Frazer MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages; and Plaintiff Margaret MacTavish, Individually, has been damaged in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages.

### SIXTH CAUSE OF ACTION

33. The Plaintiffs reallege and restate as if fully incorporated herein Paragraphs 1 through 32 and for their Sixth Cause of Action state as follows.

34. The foregoing acts and omissions of the Defendant were willful, wanton and grossly negligent and caused, directly and proximately, the injuries to Plaintiffs as aforementioned, all to which Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, have been damaged in the amount of Twenty Two Million Five Hundred Thousand (\$22,500,000.00) Dollars punitive damages; Plaintiff Neil Frazer MacTavish, Individually, has been damaged in the amount of Ten Million (\$10,000,000.00) Dollars punitive damages; and Plaintiff Margaret MacTavish, Individually, has been damaged in the amount of Ten Million (\$10,000,000.00) Dollars punitive damages.

WHEREFORE, Plaintiffs Neil Frazer MacTavish and Margaret MacTavish, as Next Friends and Guardians of Neil MacTavish, a Minor, demand Judgment against the Defendant in the amount of Ten Million (\$10,000,000.00) Dollars compensatory damages and Twenty Two Million Five Hundred Thousand (\$22,500,000.00) Dollars punitive damages; Plaintiff Neil Frazer MacTavish, Individually, demands Judgment against the Defendant in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages and Ten Million (\$10,000,000.00) Dollars punitive damages; and Plaintiff Margaret MacTavish, Individually, demands Judgment against the Defendant in the amount of Five Million (\$5,000,000.00) Dollars compensatory damages and Ten

Million (\$10,000,000.00) Dollars punitive damages. Plaintiffs also demand all costs, interest and attorneys fees, and all other relief to which they may be entitled.

WAITE, SCHNEIDER, BAYLESS  
& CHESLEY CO., L.P.A.

/s/ STANLEY M. CHESLEY  
1318 Central Trust Tower  
Cincinnati, Ohio 45202  
TRIAL COUNSEL FOR PLAINTIFFS

George A. Kokus  
COHEN AND KOKUS  
1521 N.W. 15th Street Road  
Miami, Florida 33125  
CO-COUNSEL FOR PLAINTIFFS

Allen T. Eaton  
COHEN AND KOKUS  
Washington D.C. Office  
1025 Vermont Avenue, N.W.  
Suite 503  
Washington, D.C. 20005  
CO-COUNSEL FOR PLAINTIFFS

### JURY DEMAND

The Plaintiffs herein demand a trial by jury on all issues.

/s/ STANLEY M. CHESLEY  
TRIAL COUNSEL FOR PLAINTIFFS

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

Case No. A 8307058

[Title omitted in Printing]

PETITION FOR REMOVAL

(Filed September 8, 1983)

The Petitioner Merrell Dow Pharmaceuticals Inc., hereby petitions this Court for removal of the above-entitled action from the Court of Common Pleas of Hamilton County, Ohio, to the United States District Court for the Southern District of Ohio, and respectfully states as follows:

1. That the Petitioner, Merrell Dow Pharmaceuticals Inc., is the defendant in a civil action commenced against it on September 1, 1983, in the Court of Common Pleas of Hamilton County, Ohio, entitled: "Larry James Christopher Thompson and Donna Lynn Thompson as Next Friends and Guardians of Jessica Elizabeth Thompson, et al., Plaintiffs, against Merrell Dow Pharmaceuticals Inc., (formerly known as Richardson-Merrell, Inc.), Defendant." A copy of the Complaint and Jury Demand in that action are attached hereto.

2. That the above-described action is one of which this Court has original jurisdiction under the provisions of Title 28, *United States Code*, Section 1332, and is one which may be removed to this Court by the Petitioner, defendant herein, pursuant to the provisions of Title 28, *United States Code*, Section 1441, in that it is a civil action wherein the matter in controversy exceeds the sum or value of \$10,000 exclusive of interest and costs, and is between citizens of a State and citizens or subjects of a foreign state, and is founded, in part,

on an alleged claim arising under the laws of the United States: The plaintiffs, Larry James Christopher Thompson and Donna Lynn Thompson at the time this action was commenced, were and still are citizens of Ontario, Canada, and the defendant, Merrell Dow Pharmaceuticals Inc., at the time this action was commenced, was and still is a corporation incorporated under the laws of the State of Delaware, with its principal place of business in the State of Ohio; Plaintiffs' Fourth Cause of Action alleges that defendant violated provisions of a federal statute, the Federal Food, Drug, and Cosmetics Act, cited as 52 Stat. 1040, §§ 502(a), (f)(2) & (j) and 201(n).

3. Petitioner files herewith a bond with good and sufficient surety in the sum of Two Hundred Fifty Dollars (\$250.00) conditioned as provided by Title 28, *United States Code*, Section 1446(d), that Petitioner will pay all costs and disbursements by reason of the removal proceedings hereby brought should it be determined that this action is not removable or is improperly removed.

WHEREFORE, Petitioner prays that the above-described attempted action against it in the Court of Common Pleas of Hamilton County, Ohio be removed therefrom to this Court.

Dated: September 7, 1983

Frank C. Woodside, III  
2100 Fountain Square Plaza  
511 Walnut Street  
Cincinnati, Ohio 45202  
(513) 621-6747  
Trial Counsel for Defendant,  
Merrell Dow Pharmaceuticals Inc.

OF COUNSEL:  
DINSMORE & SHOHL  
Christine L. McBroom

**AFFIDAVIT OF FRANK C. WOODSIDE, III**

STATE OF OHIO :  
 : SS:  
 COUNTY OF HAMILTON :

Frank C. Woodside, III, being duly sworn, deposes and says:

1. I am the attorney for the Petitioner herein, MERRELL DOW PHARMACEUTICALS INC., a Delaware corporation.

2. I have read the foregoing PETITION FOR REMOVAL and am informed and believe that the matters stated therein are true and on that ground allege them to be true.

Executed this 7th day of September, 1983 at Cincinnati, Ohio.

/s/ FRANK C. WOODSIDE, III

[Jurat Omitted in printing]

[Certificate of Service omitted in printing]

**UNITED STATES DISTRICT COURT  
 SOUTHERN DISTRICT OF OHIO  
 WESTERN DIVISION**

Case No. A 8307057

[Title omitted in Printing]

**PETITION FOR REMOVAL**

(Filed September 8, 1983)

The Petitioner Merrell Dow Pharmaceuticals Inc., hereby petitions this Court for removal of the above-entitled action from the Court of Common Pleas of Hamilton County, Ohio, to the United States District Court for the Southern District of Ohio, and respectfully states as follows:

1. That the Petitioner, Merrell Dow Pharmaceuticals Inc., is the defendant in a civil action commenced against it on September 1, 1983, in the Court of Common Pleas of Hamilton County, Ohio, entitled: "Neil Frazer MacTavish and Margaret MacTavish as Next Friends and Guardians of Neil MacTavish, et al., Plaintiffs, against Merrell Dow Pharmaceuticals Inc., (formerly known as Richardson-Merrell, Inc.), Defendant." A copy of the Complaint and Jury Demand in that action are attached hereto.

2. That the above-described action is one of which this Court has original jurisdiction under the provisions of Title 28, *United States Code*, Sections 1332, and is one which may be removed to this Court by the Petitioner, defendant herein, pursuant to the provisions of Title 28, *United States Code*, Section 1441, in that it is a civil action wherein the matter in controversy exceeds the sum or value of \$10,000 exclusive of interest and costs, and is between citizens of a State and citizens or subjects of a foreign state, and is founded, in part, on an alleged claim arising under the laws of the United

States: The plaintiffs, Neil Frazer MacTavish and Margaret MacTavish at the time this action was commenced, were and still are citizens or subjects of the Country of Scotland, and the defendant, Merrell Dow Pharmaceuticals Inc., at the time this action was commenced, was and still is a corporation incorporated under the laws of the State of Delaware, with its principal place of business in the State of Ohio; Plaintiffs' Fourth Cause of Action alleges that defendant violated provisions of a federal statute, the Federal, Food, Drug, and Cosmetics Act, cited as 52 Stat. 1040, §§ 502(a), (f)(2) & (j) and 201(n).

3. Petitioner files herewith a bond with good and sufficient surety in the sum of Two Hundred Fifty Dollars (\$250.00) conditioned as provided by Title 28, *United States Code*, Section 1446(d), that Petitioner will pay all costs and disbursements by reason of the removal proceedings hereby brought should it be determined that this action is not removable or is improperly removed.

WHEREFORE, Petitioner prays that the above-described attempted action against it in the Court of Common Pleas of Hamilton County, Ohio be removed therefrom to this Court.

Dated: September 7, 1983.

/s/ FRANK C. WOODSIDE, III  
2100 Fountain Square Plaza  
511 Walnut Street  
Cincinnati, Ohio 45202  
(513) 621-6747  
Trial Counsel for Defendant,  
Merrell Dow Pharmaceuticals, Inc.

OF COUNSEL:  
DINSMORE & SHOHL  
Christine L. McBroom

# AFFIDAVIT OF FRANK C. WOODSIDE, III

STATE OF OHIO

:  
: SS:

COUNTY OF HAMILTON :

Frank C. Woodside, III, being duly sworn, deposes and says:

1. I am the attorney for the Petitioner herein, MERRELL DOW PHARMACEUTICALS, INC., a Delaware corporation.

2. I have read the foregoing PETITION FOR REMOVAL and am informed and believe that the matters stated therein are true and on that ground allege them to be true.

Executed this 7th day of September, 1983 at Cincinnati, Ohio.

/s/ FRANK C. WOODSIDE, III

[Jurat Omitted in printing]

[Certificate of Service omitted in printing]

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

Civil Action No. A-8307057

[Title omitted in printing]

**PLAINTIFFS' MOTION TO REMAND  
UNDER § 1447(c) FOR LACK OF JURISDICTION**

(Filed October 14, 1983)

COME NOW the plaintiffs, by counsel, and on the basis more fully explained in the accompanying Memorandum in Support hereof, move this Court for an order remanding the above-captioned actions to the Court of Common Pleas for Hamilton County, Ohio.

Respectfully submitted,

WAITE, SCHNEIDER, BAYLESS  
& CHESLEY

By: /s/ JEROME L. SKINNER  
(S547)

1318 Central Trust Tower  
Fourth and Vine Streets  
Cincinnati, Ohio 45202  
(513) 621-0267

/s/ GEORGE A. KOKUS, ESQ.  
COHEN & KOKUS  
1521 N.W. 15th Street Road  
Miami, Florida 33125

/s/ ALLEN T. EATON, ESQ.  
ALLEN T. EATON &  
ASSOCIATES  
1025 Vermont Avenue, N.W.  
Suite 503

Washington, D.C. 20005  
Counsel for Plaintiffs

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

Civil Action No. A-8307057

[Title omitted in printing]

**MEMORANDUM IN SUPPORT OF  
PLAINTIFFS' MOTION TO REMAND  
UNDER § 1447(c) FOR LACK OF JURISDICTION**  
(Filed October 14, 1983)

**I. Procedural History**

Plaintiffs, residents of Scotland, filed the subject actions on September 1, 1983, in the Court of Common Pleas in Hamilton County, Ohio. On or about September 7, 1983, defendant filed a removal petition in this Court with the requisite bond. Plaintiffs, through this motion, seek an order under 28 U.S.C. § 1447(c) remanding the actions to the state court and requiring the defendants to pay plaintiffs, in accordance with 28 U.S.C. § 1446, costs and disbursements incurred by reason of the removal proceedings.

**II. Operative Facts**

Plaintiffs are residents of Scotland, United Kingdom, who allege that their children suffered birth defects as the result of the ingestion of Debendox during pregnancy. Debendox is the British trade name for the antinauseant morning sickness drug Bendectin manufactured by defendant Merrell. Plaintiffs allege, *inter alia*, that defendant Merrell violated certain provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. § 301-*et seq.* (52 Stat. 1040-*et seq.*)<sup>1</sup>

<sup>1</sup> Case numbers are A83-07057 and A83-07058. Copies of the complaints are attached hereto and incorporated herewith by reference to defendant's removal petition (Exhibit A).

In their Fourth Cause of Action, plaintiffs allege that defendant violated 21 U.S.C. § 352 when it sold Debendox (a/k/a Bendectin) in a branded and defective condition. Plaintiffs allege in paragraph 26 of their complaints that Merrell's violation of the Food, Drug and Cosmetic Act in promoting of Debendox constituted a rebuttable presumption of negligence.<sup>2</sup>

Defendants suggest that by asserting violations of the Food, Drug and Cosmetic Act, plaintiffs' claims arise under the laws of the United States, and thereby give this Court original jurisdiction under 28 U.S.C. § 1331 and provide the basis for removal under 28 U.S.C. § 1441(b).

### III. Issues Presented

- A. Do plaintiffs' claims arise under the laws of the United States in the sense of 28 U.S.C. § 1331?
- B. Are there any other legally cognizable grounds for removal?
- C. Should the cases be removed?

### IV. Discussion

- A. Allegations made in plaintiff's complaints do not provide a basis for federal question jurisdiction under 28 U.S.C. § 1331.

<sup>2</sup> Under Ohio law, violation of a safety statute is negligence *per se*, rendering the actor liable to plaintiff if his negligence caused or contributed to causing the plaintiff's injury. Plaintiffs will amend their complaint to include this allegation.

See *Freeman v. United States*, 509 F.2d 626 (6th Cir. 1975), in which the court held that when an injury is caused by an action which violates a safety statute, which is of the kind that the statute was intended to prevent, the action constitutes negligence *per se*.

See also *Shroades v. Rental Homes, Inc.*, 68 Ohio St.2d 20, 427 N.E.2d 774 (1981); *Zehe v. Falkner*, 26 Ohio St.2d 258, 271 N.E.2d 276 (1972). Both of these cases make clear that in Ohio it is a well-settled principle of law that a violation of a specific safety statute constitutes negligence *per se*.

In asking the Court to recognize the Food, Drug and Cosmetic Act as establishing the standard of care required of a drug manufacturer, federal jurisdiction is not vested in this Court under 28 U.S.C. § 1331. In the instant case, unlike *Cort v. Ash*, 422 U.S. 66 (1975) (private right of action principles set forth by Court) plaintiffs do not assert a federal statute as the jurisdictional basis for their claims, nor do they assert that their claims arise under the federal Food, Drug and Cosmetic Act.

Moreover, it is clear that the Act does not create a private right of action. In fact, defendant has argued in open court that there is no private right of action:

MR. LEECH: Your Honor, because there's no private right of action under the statute they are citing, and the cases so hold you can't recover damages as an individual plaintiff for the violation of the statute. The only person that can bring an action for violation of this statute is the U.S. Attorney's office.

THE COURT: What statute?

MR. LEECH: The Federal Drug & Cosmetic Act, and the section on which the plaintiff relies, regardless what they prove, they can't recover under the statute as a separate cause of action.

*Oxendine v. Richardson-Merrell, Inc.*, No. 1245-82 (Superior Ct., District of Columbia, Transcript May 2, 1983, pp. 147-48) (Exhibit B).

Similarly, in the *Koller* case, defendant argued that there was no private right of action under the Food, Drug and Cosmetic Act. Defendant wrote in its Memorandum in Support of Partial Summary Judgment:

Moreover, the law is clear that there is no private cause of action under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* See, e.g., *Pacific Trading Co. v. Wilson and Co.*, 547 F.2d 367, 368 (7th Cir. 1976); *Orthopedic Equipment Co. v. Eustler*, 276 F.2d 455, 460 (4th Cir. 1960); *Keil v. Eli Lilly & Co.*, 490 F.Supp. 479

(E.D.Mich. 1980); *Gelley v. Astra Pharmaceutical Products, Inc.*, 466 F.Supp. 182, 186-187 (D.Minn. 1979), *aff'd* 610 F.2d 558 (9th Cir. 1979); *State of Florida ex rel. Broward County v. Eli Lilly & Co.*, 329 F.Supp. 364, 365-366 (S.D.Fla. 1971); *Cross v. Board of Supervisors of San Mateo County*, 326 F.Supp. 634, 638 (N.D.Cal. 1968), *aff'd* 442 F.2d 362 (9th Cir. 1971); *Clairol, Inc. v. Suburban Cosmetics and Beauty Supply, Inc.*, 278 F.Supp. 859, 860-861 (N.D.Ill. 1968).

*Koller, et al. v. Richardson-Merrell, Inc.*, No. 80-1258 (U.S. District Court for the District of Columbia, Memorandum of Defendant Richardson-Merrell, Inc. In Support of Its Motion for Partial Summary Judgment Dismissing Plaintiffs' Claims for Fraud and Punitive Damages, February 5, 1982 at p. 42).

Plaintiffs' actions, to be sure, do not arise under federal law, as they do not assert a federally-created cause of action. Plaintiffs only urge that the federal Food, Drug and Cosmetic Act embodies the appropriate *standard of care* to be employed by the Ohio Court in determining if Merrell has been negligent, or if Bendectin is a defective product.

This principle of law regarding negligence *per se* has long been adopted by the courts in Ohio, and is indeed the majority rule. W. Prosser, *Law of Torts*, § 36 (4th ed. 1971); *Restatement (Second) of Torts*, §§ 285, 286, 288B; and 39 O. Jur2d Negligence §§ 43-44 (1959).

In a recent Pennsylvania case, the United States Court of Appeals for the Third Circuit, in applying Pennsylvania law that is nearly identical to the law of Ohio on negligence *per se*, held as follows:

"Under Pennsylvania law, the violation of a governmental safety regulation constitutes negligence *per se*" if the regulation "was, in part, intended to protect the interest of another as an individual [and] the interest of the plaintiff which was invaded . . . was one which the act intended to protect. Astra cannot seriously dispute that section 130.35 [of the Code of Federal Regulations implementing provisions of the Food, Drug and Cosmetic

Act] was promulgated to protect individuals such as Harrikah Stanton from precisely the type of harm that here occurred — an unexpected adverse reaction to Xylocaine. It thus would appear that Astra's failure to file the reports constituted negligence *per se*.

*Stanton v. Astra Pharmaceutical Products, Inc.*, Nos. 92-3364 and 82-3380 (3d Cir., Sept. 26, 1983, Slip Op. at 21-22) (citations omitted) (Exhibit C).

In summary, plaintiffs' claim that Merrell's violations of the federal Food, Drug and Cosmetic Act constitute negligence *per se* does not give rise to federal question jurisdiction under 28 U.S.C. § 1331. In the absence of federal question jurisdiction, there simply is no basis for removal under 28 U.S.C. § 1441.

Article III Courts have limited jurisdiction. In the absence of original subject matter jurisdiction in these cases, removal is improvident.

#### B. There is no other legally cognizable grounds for removal.

Defendant could contend that jurisdiction of this Court could be based on 28 U.S.C. § 1332. This argument, too, must fail. In *Pack v. Rich Terminal Company*, 502 F.Supp. 58 (S.D. Ohio 1980), Judge Spiegel held that if a defendant is a citizen of a state, removal from state court is improper.

Ohio is Merrell's principal place of business. Merrell is a corporate citizen of Ohio. Removal, therefore, is inappropriate under 28 U.S.C. § 1441(b).

After a careful review of the United States Code to discern any other bases for the exercise of jurisdiction by federal courts under the circumstances of this case, plaintiffs can find no colorable basis for the exercise of jurisdiction by an Article III Court.

#### C. The cases should be remanded to state court.

In the absence of original jurisdiction in the federal courts, there simply is no basis for removal. The cases, therefore,

should be remanded to state court. Finally, plaintiffs are entitled to the payment of costs and disbursements incurred because of these removal proceedings.

Respectfully submitted,  
WAITE, SCHNEIDER, BAYLESS  
& CHESLEY

By: /s/ JEROME L. SKINNER  
(S547)

1318 Central Trust Tower  
Fourth and Vine Streets  
Cincinnati, Ohio 45202  
(513) 621-0267

/s/ GEORGE A. KOKUS, ESQ.  
COHEN & KOKUS  
1521 N.W. 15th Street Road  
Miami, Florida 33125

/s/ ALLEN T. EATON, ESQ.  
ALLEN T. EATON &  
ASSOCIATES  
1025 Vermont Avenue, N.W.  
Suite 503  
Washington, D.C. 20005  
Counsel for Plaintiffs

[Certificate of Service omitted in printing]

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

Case No. C-1-83-1436

Case No. C-1-83-1437

[Title omitted in printing]

**DEFENDANT MERRELL DOW PHARMACEUTICALS  
INC.'S MEMORANDUM IN RESPONSE TO  
PLAINTIFFS' MOTION TO REMAND**

(Filed October 31, 1983)

Defendant, Merrell Dow Pharmaceuticals Inc., (hereinafter "Merrell Dow"), hereby responds to "Plaintiffs' Motion to Remand Under § 1447(c) For Lack Of Jurisdiction" (hereinafter "Plaintiffs' Motion to Remand") the two foreign plaintiff actions (Thompson and MacTavish) originally filed in the Hamilton County, Ohio Court of Common Pleas on September 1, 1983 and removed to this Court, pursuant to 28 U.S.C. § 1446(b), by way of a Petition to Remove filed September 7, 1983.

**I. FACTUAL BACKGROUND.**

Plaintiffs have also set forth the "Operative Facts" for these cases: The *MacTavish* Plaintiffs are residents of Scotland and allege in their Complaint that the infant plaintiff suffered birth defects as a result of his mother's ingestion of Debendox during pregnancy. The *Thompson* Plaintiffs are residents of Ontario, Canada and allege that the infant plaintiff suffered birth defects as a result of his mother's ingestion of Bendectin during pregnancy.

Plaintiffs have alleged violations of the federal Food, Drug

and Cosmetic Act, 21 U.S.C. §§ 201(n) and 502(a), (f)(2) and (j), in Paragraph 25 of their Complaints and claim that these violations of a federal statute constitute a rebuttable presumption of negligence.<sup>1</sup>

## II. ARGUMENT.

### A. Plaintiffs Are Merely Attempting To Circumvent This Court's Order Dismissing Similar Foreign Plaintiff Actions.

On August 24, 1982, this Court ordered the dismissal of twelve actions filed by foreign plaintiffs, all citizens of the United Kingdom.<sup>2</sup> These cases were dismissed on grounds of *forum non conveniens* and are on appeal to the United States Court of Appeals for the Sixth Circuit.<sup>3</sup> Several motions to dismiss cases filed by additional foreign plaintiffs are presently pending before this Court.<sup>4</sup> In these motions Merrell Dow

<sup>1</sup> In their Motion to Remand, Plaintiffs argue that under Ohio substantive law, this violation of a federal statute is "negligence *per se*." (Plaintiffs' Motion to Remand, n. 2). Merrell Dow does not wish to address issues irrelevant to the present controversy, however it feels compelled to discuss the issue raised concerning negligence *per se*. As argued in all foreign plaintiff cases in which Merrell Dow has filed Motions to Dismiss on grounds of *forum non conveniens*, a proper interpretation of Ohio choice-of-law rule dictates that both a federal court sitting in Ohio and the Ohio court itself would apply the laws of Scotland and Ontario, Canada to the issues of alleged negligence. Therefore, Ohio law regarding negligence *per se* would not be the authority upon which either Court would rely.

<sup>2</sup> Order and Judgment Granting Defendant's Motions To Dismiss, *Keith Neil Alexander, et al. v. Richardson-Merrell, Inc.*, and eleven other cases, Case Nos. C-1-82-285; 286; 287; 288; 289; 290; 291; 292; 293; 294; 295; and 319.

<sup>3</sup> *Steven Thomas Dowling, et al. Plaintiffs/Appellants, v. Richardson-Merrell, Inc.*, Defendant/Appellee, Consolidated Case Nos. 82-3617 through 82-3628. Oral argument is scheduled for November 30, 1983.

<sup>4</sup> *Allan Alexander Watson, et al. v. Merrell Dow Pharmaceuticals, Inc.*, *et al.* and five similarly situated cases, S.D. Ohio, Case Nos. C-1-82-327; 469; 607; 608; 609; and 611; *Peter Stewart, et al. v. Richardson-Merrell,*

has urged the Court to dismiss the cases on grounds of *forum non conveniens*, and asked this Court to adopt the same reasoning it utilized in dismissing the first twelve foreign plaintiff cases.

Merrell Dow believes that Plaintiffs in the two cases involved in these remand proceedings are attempting to circumvent the effect of this Court's Order dismissing the twelve *Alexander* cases. Plaintiffs have filed these actions in an Ohio state court in anticipation that the Sixth Circuit will affirm the *Alexander* dismissals, and upon the further expectation that this Court will similarly dismiss all foreign plaintiff cases filed against Merrell Dow where an alternative forum exists in which to more properly litigate the disputes.

### B. Merrell Dow Removed These Cases On Grounds Of Federal Question Jurisdiction, Not On Grounds Of Diversity Of Citizenship.

Plaintiffs have moved to remand these cases to the state court arguing that removal under 28 U.S.C. § 1446(b) upon grounds of diversity of citizenship is improper if the defendant is a citizen of the state. Merrell Dow does not contest the impropriety of removal of these cases to this Court based solely on grounds of diversity of citizenship.<sup>5</sup> However, the case which Plaintiffs cite as support for this argument does not apply to the basis for removal upon which Merrell Dow petitioned this Court, to wit: federal question jurisdiction.

*Inc.*, S.D. Ohio, Case No. C-1-82-426; *Vicki Elizabeth Crallan, et al. v. Merrell Dow Pharmaceuticals, Inc.*, S.D. Ohio, Case No. C-1-82-590; *Gordon Foorte Peter Vandervliet, et al. v. Merrell Dow Pharmaceuticals, Inc.*, S.D. Ohio, Case No. C-1-82-470.

<sup>5</sup> A reading and interpretation of 28 U.S.C. § 1441(a) & (b) make it clear that because Merrell Dow is a "citizen" of Ohio, in that it has its principal place of business in Reading, Hamilton County, Ohio, 28 U.S.C. § 1332(c), removal to this Court would not be proper based solely upon a diversity of citizenship basis. Merrell Dow was cognizant of the law in this Circuit when it filed the Petitions For Removal in these cases. *Jacobs & Co. Levin*, 86 F.Supp. 850 (N.D. Ohio 1949), *aff'd.*, 180 F.2d 356 (6th Cir. 1950).

The defendant in *Pack v. Rich Terminal Company*, 502 F. Supp. 58 (S.D. Ohio 1980), cited at page 6 of Plaintiffs' Motion to Remand, had petitioned the Court for removal alleging "federal jurisdiction based *only* on the basis of diversity. . . ." *Id.* at 59 (emphasis added). However, Merrell Dow did not petition the Court for removal based *only* on grounds of diversity of citizenship of the parties; Merrell Dow petitioned the Court to remove these cases on grounds that each Plaintiff's Fourth Cause of Action is one of which this Court has original jurisdiction, as it alleged a claim arising under the laws of the United States, and was therefore removable pursuant to 28 U.S.C. § 1441.

**C. If In Fact Plaintiffs Do Not Intend On Litigating Alleged Violations Of the Federal Food, Drug And Cosmetic Act In State Court, Merrell Dow Concedes That No Federal Question Exists In These Actions.**

It is a well-established rule of law "that federal questions in removal cases must be disclosed on the face of the *plaintiff's* complaint and must be essential to the plaintiff's cause of action. . . ." *Border City Savings & Loan Assn. v. Kennebec Mortgage & Equities, Inc.*, 523 F. Supp. 190, 192 (S.D. Ohio 1981) (original emphasis). "[I]t is the rule that to justify removal to the federal court the controlling federal question must appear directly and positively upon the complaint." *Venner v. New York Central Railroad Co.*, 203 F. 373, 374 (6th Cir. 1923). See, also, *Gully v. First National Bank in Meridian*, 299 U.S. 109, 112-13 (1936); *First National Bank of Aberdeen v. Aberdeen National Bank*, 627 F.2d 843, 849 (8th Cir. 1980); *Mountain Fuel Supply Co. v. Johnson*, 586 F.2d 1375, 1380 (10th Cir. 1978).

Plaintiffs' Fourth Causes of Action evidence a substantial federal question regarding interpretation, application, and alleged violations of the federal Food, Drug and Cosmetic Act. Indeed, the Complaints demand the right of each infant plaintiff to be compensated in the amount of \$10,000,000.00

(ten million dollars), and the right of each parent plaintiff to be compensated \$5,000,000.00 (five million dollars) for these alleged violations. This federal question appears "directly and positively" upon each of the Complaints. Therefore, Merrell Dow was completely justified in petitioning this Court to remove these cases from the state court.

Plaintiffs have moved to remand these two cases on grounds that, contrary to the allegations stated in the Fourth Causes of Action in their Complaints, the alleged violations of the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, do not give rise to a federal question so as to confer jurisdiction upon this Court. Plaintiffs argue that they are not suing Merrell Dow *under* federal law and are not asserting that a federal law is the *basis* for their claims.

"Plaintiffs' actions, to be sure, do not arise under federal law, as they do not assert a federally-created cause of action. Plaintiffs only urge that the federal Food, Drug and Cosmetic Act embodies the appropriate *standard of care* to be employed by the Ohio Court in determining if Merrell has been negligent, or if Bendectin is a defective product."

(Plaintiffs' Motion to Remand, pg. 5, original emphasis). If Plaintiffs do not intend on litigating the issues concerning allegations that Merrell Dow violated the reporting requirements of the federal Food, Drug and Cosmetic Act in a state court action, then Merrell Dow concedes that, although clear from the face of the Complaints, no federal question jurisdiction exists in these cases.

Plaintiffs' counsel have, however, alleged federal question jurisdiction under 28 U.S.C. § 1331 in numerous Bendectin cases filed against Merrell Dow in federal district courts throughout the United States.<sup>6</sup> Therefore, Merrell Dow is

<sup>6</sup> See e.g., *Irving Rosenstein, et al., v. Merrell Dow Pharmaceuticals, Inc.*, S.D. Ohio Case No. C-1-82-964 (also a foreign plaintiff action); *Terry Lawson, et al.*, S.D. Ohio Case No. C-1-83-1370 (filed Aug. 31, 1983, one

justifiably confused: Will the federal question regarding the alleged violations of the Food, Drug and Cosmetic Act be argued *only* in the Bendectin cases presently pending before this Court, and abandoned in the state court? Merrell Dow doubts that Plaintiffs intend to abandon any claims they have asserted. Thus, Merrell Dow believes that the federal question, which is patently obvious upon a review of each Complaint, confers removal jurisdiction, pursuant to 28 U.S.C. §§ 1331 and 1441(a) & (b), upon this Court.

**D. If Plaintiffs Do Not Intend On Abandoning Their Claims That Merrell Dow Violated Provisions Of The Federal Food, Drug And Cosmetics Act, Then It Is Clear That An Important Federal Question Exists In These Actions.**

As discussed previously, the determination as to whether federal question jurisdiction exists in a removal action must be discerned from the face of the Complaint. A review of Plaintiffs' Complaints clearly reveals a claim arising under the laws of the United States. 28 U.S.C. §§ 1331 and 1441(b). "Arising under" jurisdiction exists when "a properly pleaded 'state-created' claim itself presents a 'pivotal question of federal law,' for example because an act of Congress must be construed or 'federal common-law govern[s] some disputed aspect' of the claim." *State of New York v. Citibank*, 537 F. Supp. 1192, 1196 (S.D.N.Y. 1982), quoting, *McFaddin Express, Inc. v. Adley Corp.*, 346 F.2d 424, 426 (2d Cir. 1965), cert. denied, 382 U.S. 1026 (1966). Moreover, "[t]he defendant is entitled to have the case removed to federal court . . . if plaintiff is attempting to avoid having an essentially federal claim adjudicated in a federal forum merely by artfully drafting the complaint in terms of state law." *People of the State of Illinois v. Kerr-McGee Chemical Corp.*, 677 F.2d 571, 575

day before the two instant actions were filed in the state court); *Terry Watson, et al. v. Merrell Dow Pharmaceuticals, Inc.*, S.D. Ohio Case No. C-1-83-47 (originally filed in the U.S. District Court for the Eastern District of Texas).

(7th Cir. 1981). See also *Mountain Fuel Supply Co. v. Johnson*, 586 F.2d 1375, (10th Cir. 1978) ("A case 'arises' under the laws of the United States if it clearly and substantially involves a dispute or controversy respecting the validity, construction or effect of such laws which is determinative of the resulting judgment." *Id.* at 1381. (citation omitted) (emphasis added)).

Even if the Court looks beyond the face of the Complaints to Plaintiffs' Motion to Remand, federal question jurisdiction exists — irrespective of Plaintiffs' arguments to the contrary. Although Plaintiffs state that they are not suing to *enforce* the provisions of the federal Food, Drug and Cosmetic Act, they allege, nevertheless, that Merrell Dow *violated* provisions of the Act. "A suit may arise under federal law, even though a federal remedy is not sought, if the plaintiff's claim relies substantially on propositions that define federal rights, duties or relationships." *Guinasso v. Pacific First Federal Savings And Loan Assn.*, 656 F.2d 1364, 1367 n. 7 (9th Cir. 1981).

Based upon the foregoing citations of authority, and upon Merrell Dow's suspicion that Plaintiffs will attempt to raise the alleged violations of a federal statute in the state court if the actions are remanded, it is submitted that this cause of action "arises under" the laws of the United States so as to confer upon this Court federal question jurisdiction pursuant to 28 U.S.C. §§ 1331 & 1441(b).<sup>7</sup>

**E. The Court Should Not Award Plaintiffs Costs Incurred By Reason Of The Removal Proceedings.**

Title 28 U.S.C. § 1446(c) permits a court to order the payment of costs if a case is improvidently removed from a state

<sup>7</sup> Merrell Dow further submits that the remaining causes of action set forth in Plaintiffs' Complaints should be retained by this Court under pendent jurisdiction: The state and federal claims "derive from a common nucleus of operative fact," Plaintiffs "would ordinarily be expected to try them all in one judicial proceeding," and retention will accommodate "considerations of judicial economy, convenience and fairness to [the] litigants." *United Mine Workers of America v. Gibbs*, 383 U.S. 715, 725-26 (1966).

court. However, "while under the statute an award of costs against the removing party would appear to be discretionary with the district judge, courts are more inclined to assess costs when the nonremovability of the action is obvious." *Pack v. Rich Terminal Co.*, 502 F. Supp. 58 (S.D. Ohio 1980). As previously argued, the federal question upon which Merrell Dow petitioned this Court for removal is clearly stated on the face of Plaintiffs' Complaints. Merrell Dow was first made aware that Plaintiffs would argue that no federal question jurisdiction existed when it was served with Plaintiffs' Motion To Remand. Therefore, because removability is obvious from the Complaint, Merrell Dow submits that no costs should be awarded against it as a result of its filing with this Court the Petitions to Remove the *MacTavish* and *Thompson* cases.

#### IV. CONCLUSION.

For the reasons stated in this memorandum, Merrell Dow requests that the plaintiffs' Motion To Remand be overruled.

/s/ FRANK C. WOODSIDE, III  
2100 Fountain Square Plaza  
511 Walnut Street  
Cincinnati, Ohio 45202  
(513) 621-6747  
Liaison Counsel for Defendant,  
Merrell Dow Pharmaceuticals Inc.

#### OF COUNSEL:

Christine L. McBroom  
DINSMORE & SHOHL

[Certificate of Service omitted in printing]

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

Case No. C-1-83-1436

Case No. C-1-83-1437

[Title omitted in printing]

**PLAINTIFFS' REPLY TO DEFENDANT MERRELL DOW  
PHARMACEUTICALS, INC.'S MEMORANDUM  
IN RESPONSE TO PLAINTIFFS' MOTION TO REMAND**

(Filed November 22, 1983)

Plaintiffs in the above-captioned cases hereby reply to defendant Merrell Dow Pharmaceuticals, Inc.'s response to plaintiffs' motion to remand.

#### Discussion

The sole basis upon which defendant opposes plaintiffs' motion to remand is that the lawsuits at issue "arise under" the laws of the United States within the meaning of the jurisdictional statute. 28 U.S.C. § 1331 (1980).

It is evident that the causes of action in these cases arise *not* under any law of the United States, but wholly under the common law. The defendant is an Ohio corporation and the rights claimed are those of parents and children who seek redress under the common law for injuries sustained from the ingestion of defendant's drug product Bendectin (Debendox). The foundation of plaintiffs' lawsuit turns upon duties and responsibilities imposed upon defendant under the laws of negligence, strict liability, fraud and implied and expressed warranty.

The Supreme Court has made it clear that for a suit to

"arise under" the laws of the United States that the laws of the United States must *create* part of the cause of action *by their own force*. *American Well Works Co. v. Layne & Bowler Co.*, 241 U.S. 257, 260 (1916) ("A suit arises under the law that creates the cause of action."); *Gully v. First National Bank in Meridian*, 299 U.S. 109, 112 (1936) (Federal question embraced if "a right or immunity created by the Constitution or laws of the United States [is] an element, and an essential one, of the plaintiff's cause of action.")

The mere reference to a federal statute as a criterion or test, when the law of the United States has no force of its own, does not suffice to establish that a cause of action arises under the laws of the United States. *Moore v. Chesapeake & Ohio Ry.*, 291 U.S. 205 (1934). In *Moore*, plaintiff alleged injuries received when he was involved in intrastate commerce and sought recovery under the Employers' Liability Act of Kentucky. Plaintiff, as part of his complaint under the Employers' Liability Act of Kentucky asserted violations of the Federal Safety Appliance Acts. In holding that plaintiff's complaint did *not* arise under the laws of the United States, and therefore was not cognizable in federal court, the Supreme Court wrote:

The Federal Safety Appliance Acts, while prescribing absolute duties, and thus creating correlative rights in favor of injured employees, did not attempt to lay down rules governing *actions for enforcing these rights* (emphasis added).

\* \* \*

The Safety Appliance Acts having prescribed the duty in this fashion, the right to recover damages sustained by the injured employee through the breach of duty *sprang from the principle of the common law . . .* and was left to be enforced accordingly, or, in the case of the death of the injured employee, according to the applicable statute (emphasis added).

*Id.* at 215-16.

What defendant, however, fails to recognize is that the

Food, Drug & Cosmetic Act *does not create* substantive rights on behalf of plaintiffs in civil suits against drug manufacturers. Rather, it only serves as a yardstick for determining whether the manufacturer has satisfied the duty of reasonable care created under the common law of negligence.

Moreover, to suggest that the instant complaints reveal a pivotal "dispute or controversy respecting the validity, construction, or effect of [the Food, Drug & Cosmetic Act] upon the determination of which the result depends, *Shulthis v. McDougal*, 225 U.S. 561, 569 (1912),<sup>1</sup> is to read beyond the four corners of plaintiffs' complaint. The validity, construction, and/or effect of the Food, Drug & Cosmetic Act are *not* "pivotal" issues in this case; these cases allege causes of action for negligence, strict liability, fraud, and breach of implied and expressed warranties. The mere reference to a federal statute as a test or criterion does not suffice to establish that a cause of action arises under the laws of the United States, nor does it suffice to establish a pivotal dispute or controversy over the application of the Food, Drug & Cosmetic Act.

Moreover, plaintiffs' assertions that defendant has violated the Food, Drug & Cosmetic Act also can be viewed as merely replies in anticipation that defendant will raise as defenses its compliance with the provisions of the Act and the subsequent approval of the Food and Drug Administration for the marketing of Bendectin. Again, a federal question is not embraced in this instance. *Phillips Petroleum Co. v. Texaco, Inc.*, 415 U.S. 125, 127-28 (1974).

<sup>1</sup> The two cases primarily relied upon by defendant to support its position are both distinguishable from the instant cases. In *State of New York v. Citibank*, 537 F.Supp. 1192, 1196 (S.D.N.Y. 1982), the court found federal question jurisdiction where the complaint relied *exclusively* upon allegations of illegality under federal law. The complaint, in effect, sought to use state causes of action to litigate federal questions. The same cannot be said of the instant cases.

Similarly, to suggest that these cases involve *essentially federal claims* artfully drafted to avoid federal jurisdiction, *People of the State of Illinois v. Kerr-McGee Chemical Corp.*, 677 F.2d 571, 575 (7th Cir. 1981), is to misconstrue the nature of plaintiffs' complaints.

**Conclusion**

For the foregoing reasons, plaintiffs respectfully request the Court to remand these cases to the Court of Common Pleas for Hamilton County, Ohio.

Respectfully submitted,  
**ALLEN T. EATON &  
 ASSOCIATES**  
 By: /s/ JEROME L. SKINNER  
 (S547)

1318 Central Trust Tower  
 Fourth and Vine Streets  
 Cincinnati, Ohio 45202  
 (513) 621-0267

/s/ GEORGE A. KOKUS, ESQ.  
**COHEN & KOKUS**  
 1521 N.W. 15th Street Road  
 Miami, Florida 33125

/s/ ALLEN T. EATON, ESQ.  
**ALLEN T. EATON &  
 ASSOCIATES**  
 1025 Vermont Avenue, N.W.  
 Suite 503  
 Washington, D.C. 20005  
 (202) 638-4426

Counsel for Plaintiffs

[Certificate of Service omitted in printing]

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No. 85-619

Supreme Court, Ohio  
FILED

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CLERK

IN THE  
**SUPREME COURT OF THE UNITED STATES**

OCTOBER TERM, 1985

MERRELL DOW PHARMACEUTICALS INC.,  
Petitioner,

vs.

LARRY JAMES CHRISTOPHER THOMPSON AND  
DONNA LYNN THOMPSON AS NEXT FRIENDS AND  
GUARDIANS OF JESSICA ELIZABETH THOMPSON,  
LARRY JAMES CHRISTOPHER THOMPSON,  
INDIVIDUALLY AND DONNA LYNN THOMPSON,  
INDIVIDUALLY, *et al.*,  
Respondents.

On Writ of Certiorari to the  
United States Court of Appeals for the  
Sixth Circuit

BRIEF OF PETITIONER

Frank C. Woodside III  
2100 Fountain Square Plaza  
511 Walnut Street  
Cincinnati, Ohio 45202  
(513) 977-8200  
Counsel for Petitioner

Of Counsel:

John E. Schlosser  
Christine L. McBroom  
DINSMORE & SHOHL  
2100 Fountain Square Plaza  
511 Walnut Street  
Cincinnati, Ohio 45202

Petition for Certiorari filed October 11, 1985  
Certiorari Granted December 2, 1985

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## QUESTIONS PRESENTED

1. Where a plaintiff alleges that a violation of a specific federal regulatory statute constitutes a rebuttable presumption of negligence and that such violation directly and proximately caused injury to plaintiff, does such claim "necessarily depend" on resolution of an issue of federal law, so as to vest subject matter jurisdiction in the district court?

2. Where a claim which "necessarily depends" on resolution of an issue of federal law is joined with other claims not based on federal law, which would, if plaintiff prevails, obviate the federal question, does the pendency of such local claims deprive the district court of jurisdiction?

## LIST OF PARTIES

The caption of the case in this Court does not reflect that there are two cases involved in this matter. The cases were decided together by the District Court and were consolidated by the Court of Appeals. The names of the Respondents in the second case are Neil Frazer MacTavish and Margaret MacTavish as next friends and guardians of Neil MacTavish, Neil Frazer MacTavish, individually, and Margaret MacTavish, individually.

Petitioner is a subsidiary of The Dow Chemical Company. The following subsidiaries and affiliates of The Dow Chemical Company have outstanding securities in the hands of the public: Dow Banking Corporation; Dow Chemical Iberica S.A.; Gruppo Lepetit S.p.A.; Ivon Watkins-Dow Limited; Laboratorios Industriales Farmaceuticos Ecuatorianos; Merrell Toraude et Compagnie; Oronzio De Nora Impianti Elettrochimici S.A.; and Pacific Chemicals Berhad.

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No. 85-619

IN THE  
**SUPREME COURT OF THE UNITED STATES**

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OCTOBER TERM, 1985

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MERRELL DOW PHARMACEUTICALS INC.,  
Petitioner,

vs.

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DONNA LYNN THOMPSON AS NEXT FRIENDS AND  
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INDIVIDUALLY AND DONNA LYNN THOMPSON,  
INDIVIDUALLY, *et al.*,  
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On Writ of Certiorari to the  
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**BRIEF OF PETITIONER**

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Petitioner is a subsidiary of The Dow Chemical Company. The following subsidiaries and affiliates of The Dow Chemical Company have outstanding securities in the hands of the public: Dow Banking Corporation; Dow Chemical Iberica S.A.; Gruppo Lepetit S.p.A.; Ivon Watkins-Dow Limited; Laboratorios Industriales Farmaceuticos Ecuatorianos; Merreil Toraude et Compagnie; Oronzio De Nora Impianti Elettrochimici S.A.; and Pacific Chemicals Berhad.

### OPINIONS AND JUDGMENTS BELOW

The opinion of the Court of Appeals is reported at 766 F.2d 1005 (6th Cir. 1985) and is printed in the Joint Appendix ("J.A.") at 8-10. The judgment of the Court of Appeals is printed at J.A. 6-7. The opinion of the District Court is unreported and is printed at J.A. 13-16. The judgments of the district court are printed at J.A. 11-12.

### JURISDICTION

The judgment of the United States Court of Appeals for the Sixth Circuit was entered and filed on July 15, 1985. J.A. 6-7. The 90th day after such judgment was Sunday, October 13, 1985. The petition for a writ of certiorari was filed October 11, 1985, and was timely under 28 U.S.C. § 2101(c). The petition for a writ of *certiorari* was granted by an Order filed December 2, 1985. This Court has jurisdiction to review the judgment of the Court of Appeals by writ of *certiorari* under 28 U.S.C. §§ 1254(1), 2101(c).

### STATUTORY PROVISIONS INVOLVED

This case involves allegations of violations of certain sections of the Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1040, as amended, 21 U.S.C. § 301, *et seq.*, which are contained in Respondents' complaints printed at J.A. 17-26, 27-35, and are set forth verbatim in the Appendix to the Petition for a Writ of Certiorari at 10a-11a, or set forth in the body of this brief.

## STATEMENT OF THE CASE

### The Parties

Petitioner Merrell Dow Pharmaceuticals Inc. (formerly known as Richardson-Merrell, Inc.) is a Delaware Corporation with its principal place of business in Hamilton County, Ohio. The Respondents are Larry James Christopher Thompson and Donna Lynn Thompson, Canadian citizens residing in Napanee, Ontario, and Neil Frazer MacTavish and Margaret MacTavish, British subjects residing in LinLithgow, Scotland. On September 1, 1983, the Thompsons and MacTavishs brought separate suits against the Petitioner in the Court of Common Pleas, Hamilton County, Ohio, at Cincinnati. They sued both individually and as next friends of their minor children, Jessica Thompson and Neil MacTavish.

### The Complaints

The Respondents are represented by the same counsel. Their complaints are identical in legal theory and structure and nearly identical in language. Respondents allege that their minor children were born with birth defects as a result of their mothers' ingestion, during pregnancy, of Bendectin, a prescription drug made and marketed in the United States by Petitioner.<sup>1</sup>

Each complaint consists of six numbered "causes of action." The first three respectively allege negligence, breach of express and implied warranties and strict liability in tort. The Sixth Cause of Action alleges gross negligence and asserts a claim for punitive damages. The Fourth and Fifth Causes of Action, however, are not so easily categorized.

<sup>1</sup> In moving for remand to state court, Respondents admitted that they did not claim to have taken Bendectin made in the United States by Petitioner, but Debendox, a similar drug made in the United Kingdom and sold by a subsidiary of Petitioner in that nation. Petitioner did not make or sell Debendox, nor did it make or sell Canadian "Bendectin," the only similar drug available to Mrs. Thompson in Ontario. Respondents' undisclosed (and factually inaccurate) equation of American Bendectin with Debendox and the Canadian drug is a consistent feature of their complaints.

The Fourth Cause of Action quotes, cites to or paraphrases numerous provisions of the Federal Food, Drug and Cosmetic Act, 52 Stat. 1040, 21 U.S.C. § 301, *et seq.* The last three paragraphs of the Fourth Cause of Action state:

25. That the promotion of said drug, Bendectin, by the Defendant for the use in females during the time period in controversy, without revealing or attempting to reveal any facts material to consequences which may result in the unborn offspring of mothers receiving the drug, constituted misbranding of said pharmaceutical drug per sub-sections (a), (f)(2) and (j) of § 502 and (n) of § 301 of 52 Stat 1040.

26. That violation of said Federal Statutes in the promotion of said drug, Bendectin, by the Defendant herein enumerated, constitutes a rebuttable presumption of negligence.

27. That the Defendant's violation of said Federal Statutes directly and proximately caused the injuries suffered by said Minor. . . .

J.A. 22-23, 32 (emphasis added).

The Fifth Cause of Action alleges, *inter alia*,

31. The Defendant failed to submit all relevant data bearing on the safety of the drug Bendectin to the Food & Drug Administration, as required by law.

32. That the acts and omissions of the Defendant, as aforementioned, directly and proximately caused the injuries suffered by said Minor. . . .

J.A. 23-24, 33 (emphasis added).

#### Proceedings In The District Court

Petitioner filed timely petitions for removal from the Common Pleas Court to the U.S. District Court for the Southern District of Ohio, Western Division. Those petitions alleged, as a ground for removal, that Respondents' Fourth Cause of Ac-

tion was "an alleged claim arising under the laws of the United States. . . ." J.A. 37, 39-40. Respondents thereafter filed a joint motion to remand these cases to the state court for want of federal jurisdiction. J.A. 42-48. In support of this motion, Respondents stated, in part:

Plaintiffs' actions, to be sure, do not arise under federal law, as they do not assert a federally-created cause of action. Plaintiffs only urge that the federal Food, Drug and Cosmetic Act embodies the appropriate *standard of care* to be employed by the Ohio Court in determining if Merrell has been negligent, or if Bendectin is a defective product.

This principle of law regarding negligence *per se* has long been adopted by the courts in Ohio, and is indeed the majority rule [Citations omitted].

\* \* \*

In summary, plaintiffs' claim that Merrell's violations of the federal Food, Drug and Cosmetic Act constitute negligence *per se* does not give rise to federal question jurisdiction under 28 U.S.C. § 1331.

J.A. 46-47.

Respondents' motion to remand additionally stated:

Plaintiffs are residents of Scotland, United Kingdom, who allege that their children suffered birth defects as the result of the ingestion of Debendox during pregnancy. Debendox is the British trade name for the antinauseant morning sickness drug Bendectin manufactured by defendant Merrell. Plaintiffs allege, *inter alia*, that defendant Merrell violated certain provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. § 301-*et seq.* (52 Stat. 1040-*et seq.*) [Footnote omitted.]

In their Fourth Cause of Action, plaintiffs allege that defendant violated 21 U.S.C. § 352 when it sold Debendox (a/k/a Bendectin) in a branded [sic] and defective

condition. Plaintiffs allege in paragraph 26 of their complaints that Merrell's violation of the Food, Drug and Cosmetic Act in promoting of Debendox constituted a rebuttable presumption of negligence. [Footnote omitted.]

J.A. 43-44.

"Debendox" was a familiar name to both courts below, though it had not been mentioned in either of Respondents' complaints. Like Bendectin of American make, Debendox is a drug indicated for "morning sickness." Its formulation has varied over time and has not always been the same as that of the American drug.<sup>2</sup> One year before the filing of Respondents' complaints, the District Court had dismissed, on grounds of *forum non conveniens*, twelve suits brought by British subjects against the Petitioner alleging that Debendox had caused their children's birth defects. *In Re Richardson-Merrell Inc.*, 545 F. Supp. 1130 (S.D. Ohio 1982), *aff'd sub nom. Dowling v. Richardson-Merrell Inc.*, 727 F.2d 608 (6th Cir. 1984). The opinion of the Circuit Court describes the history of Debendox including its manufacture in the United Kingdom (by a corporation unrelated to Petitioner) and its sale and distribution in that nation by a wholly-owned subsidiary of the Petitioner, 727 F.2d at 611, *though not by Petitioner, itself*.<sup>3</sup>

The British plaintiffs in *Dowling v. Richardson-Merrell Inc.*, (who were represented on appeal by Respondents' counsel) had taken an approach to their pleadings different from the Respondents. The *Dowling* plaintiffs originally filed their suits in federal court based upon diversity of citizenship. Unlike Respondents, they had made no pretense of having

<sup>2</sup> As is apparent from an examination of the *Thompson* complaint, J.A. 17-25, the Thompsons are Canadian rather than United Kingdom citizens. A third drug, of Canadian manufacture, was sold in Canada and bore the name, "Bendectin", though it also varied in formulation from the American drug made by Petitioner.

<sup>3</sup> During the era of Mrs. Thompson's claimed ingestion of the drug, Canadian Bendectin was made and sold in Canada by Petitioner's subsidiary, though not by Petitioner itself.

taken an American made drug. They did not allege or rely upon a violation of the Food, Drug and Cosmetic Act.

Respondents' complaints were filed one year after the District Court had dismissed the *Dowling* suits on grounds of *forum non conveniens*. J.A. 17, 27. Respondents did not then allege that they had taken Debendox, but directly asserted that their obstetricians had prescribed and that they had taken Bendectin and that such was a drug made in the United States by the Petitioner. J.A. 18, 28. Debendox was not mentioned in either complaint.

Petitioner opposed remand on the same grounds asserted herein. While Respondents' motion to remand was pending, Petitioner moved to dismiss both suits on grounds of *forum non conveniens*, relying upon the above-described precedents. In support of its motions to dismiss, Petitioner relied upon affidavits it had filed in a motion to dismiss an Ontario, Canadian-plaintiff action, *Vandervliet v. Merrell Dow Pharmaceuticals Inc.*, S.D. Ohio, Case No. C-1-82-470 (Affidavit of William A. Robertson) and *Alexander v. Richardson-Merrell Inc.*, S.D. Ohio, Case No. C-1-82-285. (Affidavit of Thomas Ronald Irwin, Supplemental Record, Defendant's Appendix To The Pending *Forum Non Conveniens* Motion, Exhibit 5.) *Alexander* was one of the *Dowling* cases. *Vandervliet* alleged a birth defect resulting from use of Canadian Bendectin. This procedure of incorporation by reference was specifically ordered by the District Court in the "Bendectin" cases in order to reduce the volume of redundant filings in cases presenting identical issues. The affidavits offered in this manner showed the British and Canadian origin of Debendox and Canadian Bendectin and their manufacture and sale by companies other than Petitioner during the pregnancies of Mrs. Thompson and Mrs. MacTavish.

In a single opinion, the District Court denied the Respondents' Motion to Remand and granted the Petitioner's motions to dismiss on grounds of *forum non conveniens*. J.A. 13-16. Addressing the jurisdictional question, the District Court stated:

Applying the rule as stated in *Smith* [*Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921)], the Court concludes that federal-question jurisdiction exists over these cases and that they were properly removed. Although plaintiffs' fourth cause of action is technically a claim for negligence pursuant to state law, the sole basis for the claim is the alleged violation of the federal Act by defendant. Therefore, the key issue with respect to that cause of action is whether defendant's conduct violated the Act. Phrased in terms of the *Smith* standard, plaintiffs' "right to relief depends upon the . . . application of the . . . laws of the United States."

J.A. 15-16.

### The Appeal

Respondents appealed, devoting the entirety of their briefs on appeal to the jurisdictional issue.<sup>4</sup> The Court of Appeals reversed the decision of the District Court on jurisdictional grounds and remanded the Respondents' cases to the District Court with instructions to remand the same to state court. The Court of Appeals stated:

[A] case removed to federal court under the guise of federal question jurisdiction presents a federal question when it "arises under" federal law. In *Franchise Tax Board*, [*Franchise Tax Board v. Construction Laborers' Vacation Trust*, 463 U.S. 1 (1983)] the Court stated:

Under our interpretations, Congress has given the lower courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a well pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law.

*Id.* at 2856. [463 U.S. at 27-28].

<sup>4</sup> Because respondents did not argue the issue of *forum non conveniens* in the Sixth Circuit, such issue is not before this Court. *City of Eastlake v. Forest City Enterprise, Inc.*, 426 U.S. 668, 671 n.2 (1976).

The parties agree that the FDCA does not create or imply a private right of action for individuals injured as a result of violations of the Act. Federal question jurisdiction would, thus, exist only if plaintiffs' right to relief depended necessarily on a substantial question of federal law. Plaintiffs' causes of action referred to the FDCA merely as one available criterion for determining whether Merrell Dow was negligent. Because the jury could find negligence on the part of Merrell Dow without finding a violation of the FDCA, the plaintiffs' causes of action did not depend necessarily upon a question of federal law. Consequently, the causes of action did not arise under federal law and, therefore, were improperly removed to federal court. See *Zeig v. Shearson/American Express, Inc.*, 592 F.Supp. 612, 613-14 (E.D. Va. 1984); *State of Florida ex rel. Broward County*, 329 F.Supp. 364, 366, n. 3 (S.D.Fla. 1971).

J.A. 9-10 (emphasis in original). This Court thereafter granted Petitioner's timely petition for a writ of *certiorari*.

### SUMMARY OF ARGUMENT

Respondents' complaints accuse Petitioner of causing their childrens' birth defects by "misbranding" Bendectin, Petitioner's American-made drug. Respondents allege that this violation of the Federal Food, Drug and Cosmetic Act was the proximate cause of the birth defects. In fact, and as revealed by Respondents in seeking remand, they attribute their childrens' birth defects to two foreign drugs not of Petitioner's manufacture. Their actual contention is that these foreign drugs were "misbranded" in violation of the Federal Food, Drug and Cosmetic Act. Respondents' Fourth Causes of Action are necessarily dependent on their proof of the federal violations which they allege. This essential federal element of their Fourth Causes of Action renders each suit one "arising under" federal law. In accordance with the principles articulated in *Franchise Tax Board v. Construction Laborers' Vacation Trust*, 463 U.S. 1 (1983), Respondents'

cases are within the original jurisdiction of the District Court under 28 U.S.C. § 1331, and their removal, pursuant to 28 U.S.C. § 1441(b), was proper.

Respondents' Fourth Causes of Action allege statutory violations different in character from those typically relied upon for a claim of negligence. Most claims of this type allege violations of simply worded statutes which do not require construction or interpretation. Such concise statutory requirements have sometimes prompted judicial decisions that claims of negligence based on their violation posed only factual questions, but no legal controversy requiring construction of federal law. In contrast, Respondents' complaints show that construction and interpretation of federal law will be required.

Because Respondents accuse Petitioner of "misbranding" the drugs they took by issuing misleading promotional literature on the drug, proof of their claims would require a demonstration that Petitioner's promotional literature did not comply with the Food, Drug and Cosmetic Act and with applicable federal regulations governing advertising of prescription drugs. They invoke a complex regulatory statute rather than a simply worded statute of obvious meaning. On their face, Respondents' complaints show that construction and interpretation of the federal statute will be necessary. This is only more obvious in light of Respondents' admission that they actually attribute their children's birth defects to foreign-made drugs rather than to American-made Bendectin. Respondents' inaccurate characterization of their own claims obscures an essential premise of those claims, i.e., that Petitioner could be responsible for the "misbranding" of drugs made and sold in foreign countries by concerns other than itself. This novel federal proposition, on which their Fourth Causes of Action depend, even more clearly presents a federal question conferring jurisdiction over their claims.

While Respondents' negligence claims are not federally created, they do necessitate the construction and interpretation of federal law, as noted above. This Court has previously

declared federal jurisdiction unavailable over negligence claims premised on federal statutory violations. However, these cases concerned the Safety Appliance Act which, by this Court's prior decisions, is to be applied without construction or interpretation which might dilute its clear and literal requirements. Furthermore, this Court in *Franchise Tax Board* discarded the premise of these earlier decisions, that only a federally created claim could arise under federal law. The view that a state-created claim can, in no event, arise under federal law was rejected in *Franchise Tax Board*.

The Court of Appeals, in holding that federal jurisdiction was lacking, did not contradict or analyze the District Court's conclusion that Respondents' Fourth Causes of Action were necessarily dependent on the alleged violations of the Food, Drug and Cosmetic Act. Rather, it denied jurisdiction because Respondents had the potential for recovery under their nonfederal claims of negligence, as set forth in their First Causes of Action, and that, accordingly, their "right to relief" did not "necessarily depend" on resolution of the federal question. The Court of Appeals erred in analyzing Respondents' causes of action collectively rather than individually.

It is sufficient to create federal jurisdiction that one claim in Respondents' suits necessarily depends on a substantial question of federal law. It is of no consequence that other claims on which Respondents might recover are not so dependent. The established principle of pendent jurisdiction is that claims arising under federal law should be tried in the same action as those nonfederal claims which arise out of the same occurrences. The potential that a plaintiff will achieve the relief which he seeks based solely on nonfederal grounds cannot deprive the court of jurisdiction over claims which do arise under federal law.

## ARGUMENT

**I. WHERE A PLAINTIFF ALLEGES THAT A VIOLATION OF A SPECIFIC FEDERAL REGULATORY STATUTE CONSTITUTES A REBUTTABLE PRESUMPTION OF NEGLIGENCE AND THAT SUCH VIOLATION HAS DIRECTLY AND PROXIMATELY CAUSED PLAINTIFF'S INJURIES, SUCH CLAIM "NECESSARILY DEPENDS" ON RESOLUTION OF A SUBSTANTIAL ISSUE OF FEDERAL LAW, SO AS TO VEST SUBJECT MATTER JURISDICTION IN THE DISTRICT COURT.**

- A.** The District Court correctly ruled that the Respondents' Fourth Cause of Action, which alleged Petitioner's liability by reason of its violation, through "misbranding" of Bendectin, of the Food, Drug and Cosmetic Act was a claim necessarily dependent on a substantial issue of federal law and was, therefore, one "arising under" federal law in accordance with 28 U.S.C. § 1331.

In finding that it had jurisdiction over the Respondents' claims, the District Court recognized that the Respondents could not recover on their Fourth Causes of Action without demonstrating that the Petitioner had violated the Food, Drug and Cosmetic Act. Ruling that this necessary federal element was sufficient to sustain subject matter jurisdiction under 28 U.S.C. § 1331, the District Court expressly relied upon the decision of this Court in *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983). In *Franchise Tax Board*, this Court considered a suit removed from state court to determine whether the case was one "arising under" the laws of the United States. This Court summarized the rule of law governing "federal question" jurisdiction by the following words:

Under our interpretations, Congress has given the lower federal courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a well-pleaded complaint establishes either that federal law creates the cause of action *or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law.*

*Id.* at 27-28 (emphasis added).

In *Franchise Tax Board*, this Court also paraphrased the alternate ground for federal jurisdiction under 28 U.S.C. § 1331 in several ways:

We have often held that a case "arose under" federal law, *where the vindication of a right under state law necessarily turned on some construction of federal law*, see, e.g., *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921); *Hopkins v. Walker*, 244 U.S. 486 (1917). . . . Leading commentators have suggested that for purposes of § 1331 an action "arises under" federal law "if in order for the plaintiff to secure the relief sought he will be obliged to establish both the correctness and the applicability to his case of a proposition of federal law." . . . "[A] case may 'arise under' a law of the United States if the complaint discloses a need for determining the meaning or application of such a law."

[A] right or immunity created by the Constitution or laws of the United States *must be an element, and an essential one, of the plaintiff's cause of action.*" *Gully v. First National Bank in Meridian*, 299 U.S. 109, 112 (1936).

As an initial proposition, then, the "law that creates the cause of action" is state law, and original federal jurisdiction is unavailable *unless it appears that some*

*substantial, disputed question of federal law is a necessary element of one of the well-pleaded state claims, or that one or the other claim is "really" one of federal law.*

Even though state law creates appellant's causes of action, its case might still "arise under" the laws of the United States *if a well-pleaded complaint established that its right to relief under state law requires resolution of a substantial question of federal law in dispute between the parties.*

*Id.* at 9, 10, 11, 13 (emphasis added).

The Respondents' Fourth Causes of Action, as pled, were centered solely on their allegation that the Petitioner had violated the Food, Drug and Cosmetic Act by "misbranding" Bendectin. In order to secure the relief sought in the Fourth Cause of Action, Respondents would be obliged to show "the correctness and the applicability" to their case of their proposition that Petitioner "misbranded" Bendectin in violation of the Food, Drug and Cosmetic Act. Such proposition is "an element, and an essential one" of their cause of action. Furthermore, their "rights" asserted in the Fourth Cause of Action will necessarily turn on the Court's construction of the Food, Drug and Cosmetic Act.

**B. The court which tries the Respondents' Fourth Cause of Action will be required to construe and interpret the Food, Drug and Cosmetic Act.**

The Respondents, in their First Causes of Action (which are incorporated by reference in their Fourth Causes of Action) specifically allege that the plaintiff mothers experienced nausea during pregnancy for which their obstetricians prescribed Bendectin. J.A. 18, 28. They also allege that Bendectin is a prescription drug made and distributed by the Petitioner. *Id.*

Though Respondents do not specifically cite to it, the sec-

tion of the Act which actually prohibits "misbranding" is 21 U.S.C. § 331 (52 Stat. 1042), as amended. Section 331 states, in pertinent part:

The following acts and the causing thereof are prohibited:

- (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
- (b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.
- (c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

Respondents do not cite to any of the above-quoted provisions, nor do they allege which of them the Petitioner violated. They do not allege that the drugs which they took had moved in interstate commerce or had been delivered for introduction into interstate commerce. However, to show that the drugs that they supposedly took were "misbranded," Respondents would seemingly be obliged to prove as much.

Respondents rather rely upon those sections of the Act which define misbranding. They cite to the following provision of 21 U.S.C. § 352 (52 Stat. 1050, § 502A.)

**§ 352. MISBRANDED DRUGS AND DEVICES.**

A drug or device shall be deemed to be misbranded —

- (a) If its labeling is false or misleading in any particular

\* \* \*

- (f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or

against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users.

\* \* \*

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

Respondents also cite and partially quote, in their Fourth Causes of Action, to section 201 of the Act, 21 U.S.C. § 321, 2 Stat. 1041, § 201, which, in its current form, reads:

(n) If an article is alleged to be misbranded because the labeling *or advertising* is misleading, then in determining whether the labeling *or advertising* is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling *or advertising* fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling *or advertising* relates under the conditions of use prescribed in the labeling *or advertising* thereof or under such conditions of use as are customary or usual.

(Emphasis added.)

In Paragraph 20 of their respective Fourth Causes of Action, Respondents quote to an outdated version of this statutory provision which did not include the words "or advertising". Nonetheless, the Respondents' allegation of "misbranding" in Paragraph 20 is expressly premised on "the *promotion* of said drug, Bendectin, by the defendant . . . without revealing or attempting to reveal any facts, material to consequences which may result to the unborn offspring of mothers receiving the drug. . . ." J.A. 22, 32 (emphasis added).

What the Respondents mean by the "promotion of said

drug" is not specified in their Fourth Causes of Action. However, in Paragraph 29 of their Fifth Causes of Action, they allege Petitioner's "false and fraudulent representations of fact as to the safety, nontoxicity, and freedom from side-effects of its product Bendectin . . . made in promotional literature, product inserts and by detailmen to prescribing physicians." J.A. 23, 33.

Since the Respondents do not allege that they received any label (misleading or not) prepared by the Petitioner, nor any product insert (such inserts often do not accompany drugs dispensed by prescription) it is presumably based on the promotional efforts of the Petitioner that Respondents deem the drugs they took "misbranded."

Only one section of 21 U.S.C. § 352 may render a drug "misbranded" based upon advertisements and promotional literature. 21 U.S.C. § 352(n) provides, in pertinent part, that a drug is "misbranded":

In the case of any prescription drug *distributed or offered for sale in any State*, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of . . . (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 371(e) of this title . . . .

(Emphasis added.)

Under this section, Respondents would be obliged to show that the information included in any advertisements by Petitioner failed to comply with regulations issued by the Secretary in accordance with section 352(n). To judge the compliance of the advertisements regarding Bendectin with applicable regulations requires construction and interpretation of those regulations.

Furthermore, section 503 of the Act, 21 U.S.C. § 353, exempts many prescription drugs from a number of the branding requirements of section 352. Such provisions, in pertinent part, state:

(b)(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except subsections (a), (i)(2) and (3), (k), and (l) of said section, and the packaging requirements of subsections (g), (h), and (p) of said section, if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

By reason of this provision, a pharmacist who fills a prescription and includes the usual data appearing on the prescription labels commonly issued in this country thereby sells a drug which is, by definition, *not* misbranded, at least in terms of advertising.

Mrs. Thompson and Mrs. MacTavish each allege that they took Bendectin pursuant to the prescription of a physician. J.A. 18, 28. Assuming that the pharmacist or chemist who filled the prescription did so by means of the procedure universally followed in the United States, and assuming that the Respondents' obstetricians were duly licensed to prescribe drugs, many subsections of section 352 of the Act become unavailable to the Respondents to support their allegation of misbranding. Among these are subsections (f)(2) and (j) upon which they expressly rely and subsection (n), the only provision defining false advertising as "misbranding."

Respondents' claim that Bendectin was "misbranded" through misleading promotion of that drug is a far cry from the typical claim that a statutory violation constitutes negligence. Such claims ordinarily rely on statutes which are concise and self-explanatory. The meaning of such statutes does not depend on an understanding of the governmental policies underlying their enactment. The defendant is normally accused of a discrete act or omission which would violate a clear and concrete prohibition. In contrast, Respondents' accusation requires an evaluation of the entire promotional program employed by Petitioner and a weighing of that program against the statute's objectives and those of the regulations implementing it. By its nature, Respondents' accusation presents a mixed question of law and fact, requiring judicial interpretation of the statute and regulations.

These issues of statutory construction and interpretation were never considered below because of the dismissal of Respondents' cases for *forum non conveniens*. However, when the Respondents decided to accuse Petitioner of misbranding prescription drugs by issuing misleading promotional information, they pled a cause of action which will require such consideration, whether in federal court or elsewhere. They thus embraced legal propositions that do not rely upon settled law, but raise new implications concerning the scope of a complex regulatory statute. A federal court should decide these issues.

Respondents' complaints, on their face, promise a need for construction and interpretation of the Food, Drug and Cosmetic Act. The fact that they actually attribute their children's birth defects to Debendox, of British make, and Canadian Bendectin will also compel a decision as to whether the Act applies beyond this nation's borders. The court which tries Respondents' suits will be obliged to consider several issues of the extraterritorial significance of the Food, Drug and Cosmetic Act. Among those are the following:

1. Whether the activities of a foreign corporation

(regulated in its activities by the law of its homeland) in manufacturing, labeling and selling a drug outside the United States are, in any respect, subject to the Food, Drug and Cosmetic Act.

2. Whether an American corporation may be guilty of "misbranding" a drug made, marketed, sold and ingested in a foreign country by reason of its parent-subsidiary relationship with the foreign seller or by reason of its development, manufacture, sale and testing of a similar, predecessor drug in the United States.
3. Whether drugs which have not moved in "interstate commerce" within the terms of the Food, Drug and Cosmetic Act may nonetheless be deemed "misbranded" by reason of alleged "misbranding" of a similar predecessor drug in the United States.

It was not only Bendectin but also Debendox which Petitioner is accused of "misbranding". J.A. 43-44. The Act on its face defines as "misbranding" the issuance of misleading promotional materials, but only as to prescription drugs "distributed or offered for sale in any state". 21 U.S.C. § 321(a)(1). May the allegation that Bendectin, made and distributed in the U.S., was "misbranded," render the drugs supposedly taken by the Respondents in Canada and Scotland "misbranded" within the term of the Act? Whatever the answer, it is assuredly an interpretative question of federal law and not a fact question for the jury. The need for construction and interpretation of the Food, Drug and Cosmetic Act is clear.

Respondents' complaints, however, erroneously report ingestion of American-made Bendectin, an error admitted in seeking remand. Does the "well-pleaded complaint" rule prohibit a federal court's taking notice of the actual legal contentions of a plaintiff if the complaint obscures those contentions by factual error? In *Franchise Tax Board*, this Court stated:

Although we have often repeated that "the party who brings a suit is master to decide what law he will rely upon," *The Fair v. Kohler Die & Specialty Co.*, 228 U.S. 22, 25 (1913), it is an independent corollary of the well-pleaded complaint rule that a plaintiff may not defeat removal by omitting to plead necessary federal questions in a complaint, see *Avco Corp. v. Aero Lodge No. 735, Int'l Assn. of Machinists*, 376 F. 2d 337, 339-340 (CA 6 1967), *aff'd*, 390 U.S. 557 (1968).

463 U.S. at 22 (emphasis added). The "well-pleaded complaint" rule permits a plaintiff to avoid removal by declining to rely on federal law for his claim, *only if such reliance is not necessary and unavoidable by the nature of the claim*. Here, Respondents' reliance on federal law is clear, but the novelty of their claim for extraterritorial application of the Food, Drug and Cosmetic Act is veiled by inaccurate statements as to the name and origin of the drugs which they claim to have taken.

The 'well-pleaded complaint' rule permits a plaintiff to block federal jurisdiction by choosing not to rely on federal law. It ought not allow a similar obstruction through erroneous factual allegations. The jurisdiction of the District Court in the instant cases should be judged by the contentions revealed by Respondents in urging remand, rather than by the inaccurate allegations of their complaints. A case may become removable after a complaint is filed. 28 U.S.C. § 1446(b). It will not offend the well-pleaded complaint rule to deem the Respondents' complaints "amended" to allege the "true" allegations of their claims as of their first revelation of those allegations in their motion to remand.

Whatever view this Court may take as to whether it is bound to consider only the allegations of the complaints, such will not control the jurisdictional decision. Trial of the claimed violations of the Food, Drug and Cosmetic Act, even as applied solely to American Bendectin, will require construction and interpretation of the statute. That necessity

merely becomes more obvious when the drugs allegedly taken are properly identified as products made and sold in the foreign countries of the Respondents' residence.

**C. The federal question whether the Petitioner was guilty of "misbranding" a drug under the Food, Drug And Cosmetic Act is "substantial."**

In their complaints, Respondents allege that their children's birth defects were caused by Bendectin which had been "misbranded" by the Petitioner in violation of the Food, Drug and Cosmetic Act. In their motion to remand, they reveal their actual contention that the Petitioner is responsible for the "misbranding" of *Debendox* in violation of the same Act. Under either proposition, the federal question upon which the Respondents' Fourth Cause of Action necessarily depends is a substantial one involving unsettled law.

The Petitioner, of course, denies that it misbranded the drug which it manufactured, i.e., American-made Bendectin or that the drugs available to the Respondents (*Debendox* and Canadian-made Bendectin) were misbranded. Further, the Petitioner denies the legal premise implicit in the Respondents' Fourth Cause of Action, i.e., that it may be accused of misbranding drugs produced in other countries by companies other than itself. Petitioner, indeed, maintains that the alleged "misbranding" of *Debendox* or Canadian Bendectin is a matter totally beyond the scope of the Food, Drug and Cosmetic Act and is governed entirely by the laws of Canada and of the United Kingdom. J.A. 50. However, Respondents have not invoked Canadian or British law, but that of the United States.

The questions Respondents' claims pose are "substantial" in the sense which this Court has applied as a jurisdictional test. In *Hagans v. Lavine*, 415 U.S. 528, 536-37 (1974) (citing *Ex parte Poresky*, 290 U.S. 30, 31-32 (1933)), this Court stated that, to be insubstantial, a federal claim must be "obviously without merit" or clearly foreclosed by prior Supreme Court

precedent, "leaving no room for the inference that the questions sought to be raised can be the subject of controversy." In *Mt. Healthy City Board of Education v. Doyle*, 429 U.S. 273, 279 (1976), this Court noted:

[W]here an action is brought under § 1331, . . . jurisdiction is sufficiently established by allegation of a claim under the Constitution or federal statutes, unless it 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction. . . .' *Bell v. Hood*, 327 U.S. 678, 682 (1946); *Montana-Dakota Utilities Co. v. Northwestern Pub. Serv. Co.*, 341 U.S. 246, 249 (1951).

Quite obviously, the allegations of the Respondents' Fourth Cause of Action were not "made solely for the purpose of obtaining jurisdiction" but with an earnest purpose to the contrary. While Petitioner regards the Respondents' federal contentions as improbable, the Respondents obviously do not agree. They wish to press their claim that Petitioner may be held liable for "misbranding" and wish to do so in state court rather than federal court. Should this Court conclude that the district court lacked jurisdiction, the federal controversies raised by the Respondents' complaints will be decided in state courts.<sup>5</sup> Such issues are not frivolous on their face and, accordingly, they have sufficient substance to sustain the district court's conclusion that federal jurisdiction is present.

<sup>5</sup> Some courts have noted that, in addition to the alleged federal law violations being an essential element of the plaintiffs' state law cause of action, an action can arise under the laws of the United States if "a distinctive federal policy of a federal statute requires application of federal legal principles for its disposition." *Hages v. Aliquippa & Southern R.R. Co.*, 427 F. Supp. 889, 893 (W.D. Pa. 1977). See also *North Davis Bank v. First National Bank of Layton*, 457 F.2d 820, 823 (10th Cir. 1972); *Miller v. Standard Federal Savings & Loan Assn.*, 347 F. Supp. 185, 187 (E.D. Mich. 1972). This theory of the propriety of federal jurisdiction is particularly appropriate in the present actions because of the comprehensive nature of regulation of the pharmaceutical industry through the Federal Food, Drug and Cosmetic Act.

In *State of New York by Abrams v. Citibank, N.A.*, 537 F. Supp. 1192 (S.D.N.Y. 1982), the Court stated:

D. Where this Court and lower federal courts have rejected federal jurisdiction over claims of negligence based on federal violations, such decisions have not applied or considered the alternative basis for federal question jurisdiction recognized in *Franchise Tax Board*.

In the courts below, the Respondents relied upon certain precedents for the proposition that a claim of negligence based upon a violation of federal law is not a basis for federal jurisdiction. In fact, and as the District Court found, the cases relied upon by the Respondents are inapposite. Such cases either (1) rely upon the now-rejected view that only a federally created cause of action can sustain federal question jurisdiction, (2) were based upon the settled meaning of the federal statutes there in issue, or (3) were unwarranted extensions of earlier precedents.

1. In *Franchise Tax Board*, this Court acknowledged that a claim need not be federally created in order to "arise under" federal law.

In *Franchise Tax Board*, this Court recalled Justice Holmes' definition of "arising under" jurisdiction:

The most familiar definition of the statutory "arising under" limitation is Justice Holmes' statement, "A suit arises under the law that creates the cause of action."

Federal jurisdiction in this case is particularly appropriate, since EFTA will be construed here for the first time. No reported decision construing the statute has been found. While federal courts should assume that state courts are competent to decide federal as well as state-law questions, Congress has in its jurisdictional statutes made the federal courts an available and preferred forum for federal law issues, when a plaintiff's claim depends upon their resolution. See *England v. Medical Examiners*, 375 U.S. 411, 415, 84 S. Ct. 461, 464, 11 L.ED.2d 440 (1964). That policy has special force where . . . the only forum for federal corrective action in the event of erroneous decisions would be the Supreme Court of the United States, on discretionary review.

*Id.* at 1197-98.

*American Well Works Co. v. Layne & Bowler Co.*, 241 U.S. 257, 260 (1916). However, it is well settled that Justice Holmes' test is more useful for describing the vast majority of cases that come within the district court's original jurisdiction than it is for describing which cases are beyond district court jurisdiction. We have often held that a case "arose under" federal law where the vindication of a right under state law necessarily turned on some construction of federal law, see, e.g., *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921); *Hopkins v. Walker*, 244 U.S. 486 (1917), and even the most ardent proponent of the Holmes test has admitted that it has been rejected as an exclusionary principle

463 U.S. at 8-9 (citations omitted).

Despite the "well settled" principle that the Holmes "definition" is **not** exclusive, the precedents which have denied federal jurisdiction where negligence claims are founded on asserted violations of federal statutes have often done so on the implicit or explicit premise that the Holmes test is an exclusive definition of "arising under" jurisdiction. In *Jacobson v. New York, N.H. & H.R. Co.*, 206 F.2d 153 (1st Cir.), *cert. granted*, 346 U.S. 895 (1953) (solely on the question of diversity jurisdiction), *aff'd per curiam*, 347 U.S. 909 (1954), the First Circuit affirmed the district court's dismissal of a claim for wrongful death of a passenger who had been fatally injured in a railroad accident. The plaintiff had alleged negligence based upon a violation of one section of the Safety Appliance Act, i.e., 45 U.S.C. § 1. The First Circuit held that there was no private right of action for passengers under the Safety Appliance Act and that such claim, *for that reason*, did not arise under federal law so as to sustain jurisdiction under 28 U.S.C. § 1331. The Court stated:

Furthermore, it follows that where there is no diversity of citizenship such an action cannot be maintained in a

• federal district court, since the liability for damages and the corresponding private right of action, if any, are created by state law.

206 F.2d at 157 (citations omitted).

The First Circuit in *Jacobson* did not consider whether "the vindication of a right under state law necessarily turned on some construction of federal law . . .," thus to vest federal jurisdiction notwithstanding the fact that the cause of action was created by state law. *Jacobson*, in effect, applied the Holmes test as a principle of exclusion.

It is also true that this Court has, in decisions predating *Franchise Tax Board* (and perhaps also predating the appreciation of the limitations of the Holmes test as a principle of exclusion) at times reached the same result. In *Moore v. Chesapeake & Ohio Ry. Co.*, 291 U.S. 205 (1934), this Court considered a claim under the Kentucky Employers Liability Act, a statute which reenacted, with reference to intrastate railroad traffic, the provisions of the Federal Employers Liability Act (FELA).

In *Moore*, this Court sustained "jurisdiction" over a state law claim because it did *not* arise under federal law. This reversed a decision of a circuit court which had rejected "jurisdiction" over the same claim because it *had* arisen under federal law. This anomalous result was based on the view at that time that venue statutes were jurisdictional.

Moore claimed to have been injured in attempting to uncouple freight cars. He blamed his injury on a defective uncoupling lever which, he alleged, constituted a violation of the Safety Appliance Act. Pleading alternately, Moore first alleged that his injury had occurred in interstate commerce, basing his first count on the FELA. Secondly, he alleged an injury actionable under the Kentucky Act because incurred in *intrastate* commerce. The Safety Appliance Act, as then constituted, applied to all carriers engaged in interstate commerce, regardless of whether the particular rail cars were at

any particular time engaged in intrastate traffic. Moore apparently cited the alleged violation of the Safety Appliance Act as negligence *per se* under the federal statute and state law. He also urged that such violation precluded the affirmative defenses of contributory negligence and assumption of the risk.

During the era in which Moore sued, the venue statute required suits based, even in part, on "federal question jurisdiction" to be filed only in the judicial district of the defendant's residence. *Chesapeake & Ohio Ry. Co. v. Moore*, 64 F.2d 472, 475 (7th Cir. 1933), *rev'd sub. nom.*, *Moore v. Chesapeake & Ohio Ry. Co.*, 291 U.S. 205 (1934). Suits based *solely* on diversity of citizenship could be filed in either defendant's or plaintiff's place of residence. Moore sued in his home state. For his alternative claim, he had alleged both diversity of citizenship and a claim arising under the Federal Safety Appliance Act, as well as under Kentucky law. The Circuit Court took this allegation at face value and ruled: "[J]urisdiction and venue were in the district of appellant's residence, and not in the Northern District of Indiana."<sup>6</sup> 64 F.2d at 476.

This Court reversed the Circuit Court, holding that diversity was the sole basis for federal jurisdiction and ruling that the case had been properly brought in Moore's district of residence. The Court stated:

The Federal Safety Appliance Acts prescribe duties, and injured employees are entitled to recover for injuries sustained through breach of these duties. [Citation omitted]. Questions arising in actions in state courts to recover for injuries sustained by employees in intrastate commerce and relating to the scope or construction of the Federal Safety Appliance Acts are, of course, federal questions which may appropriately be reviewed in this Court. [Citations omitted]. But it does not follow that a suit brought under the state statute which defines liability

<sup>6</sup> Venue over Moore's FELA claim was founded on a special venue provision of that Act. 45 U.S.C. § 56.

ty to employees who are injured while engaged in intrastate commerce, and brings within the purview of the statute a breach of the duty imposed by the federal statute, should be regarded as a suit arising under the laws of the United States and cognizable in the federal court in the absence of diversity of citizenship. The Federal Safety Appliance Acts, while prescribing absolute duties, and thus creating correlative rights in favor of injured employees, did not attempt to lay down rules governing actions for enforcing these rights. \* \* \* [T]he Act made no provision as to the place of suit or the time within which it should be brought, or as to the right to recover, or as to those who should be the beneficiaries of recovery, in case of the death of the employee. . . .

The federal statute in the present case touched the duty of the master at a single point and, save as provided in the statute, the right of the plaintiff to recover was left to be determined by the law of the state.

We are of the opinion that the second paragraph of the complaint set forth a cause of action under the Kentucky statute and, as to this cause of action, the suit is not to be regarded as one arising under the laws of the United States. . . .

291 U.S. at 214, 215, 216, 217 (quoting *Minneapolis, St. P. & S.S. Ry. Co. v. Popplar*, 237 U.S. 369, 372 (1915)).<sup>7</sup>

This Court in *Moore* held that a state-created claim prem-

<sup>7</sup> *Moore* is also noteworthy in that it exemplifies an outmoded view of federal pendant jurisdiction. The plaintiff in *Moore* brought two claims, one directly invoking the Federal Employers Liability Act, a claim as to which the court found a specific grant of federal jurisdiction under that Act, i.e., 45 U.S.C. § 56. The plaintiff had alternatively pled that *the same injury* was incurred in intrastate commerce, invoking the Kentucky act. Today, the jurisdiction of the court over *Moore's* alternative state claim would be readily found under the principles of pendant jurisdiction. *United Mine Workers v. Gibbs*, 383 U.S. 715 (1966).

ised on a federal violation did not "arise under" federal law. The effect of that ruling was to sustain venue, and, hence, jurisdiction over that claim. No party argued as a ground of jurisdiction, that *Moore's* Kentucky law claim was necessarily dependent on his allegation of a violation of the Safety Appliance Act. This Court did not consider such a basis for jurisdiction.

*Moore* applied the Holmes test for federal question jurisdiction as an exclusive test. All the holding really "excluded" in that case, was the defendant's venue objection. Had this Court in *Moore* considered that jurisdiction might rest on an essential question of federal law included in the Kentucky claim, it would not necessarily have reached the same result. As noted below, the Safety Appliance Act had been often litigated prior to *Moore*, and this Court had expressed the view that the statute was clear and that its provisions permitted no construction or interpretation. It is questionable whether this Court would have found jurisdiction under the alternate ground of jurisdiction discussed in *Franchise Tax Board*.

In its broad rule of law, *Moore* weighs against the Petitioner's position. However, this Court's recent ruling in *Franchise Tax Board* amends the implicit assumption in *Moore* that no state-created claim can "arise under" federal law. The peculiar facts in *Moore*, the settled meaning of the federal statutes there in issue, and *Franchise Tax Board* all compel the conclusion that *Moore* should not control the jurisdictional decision in the instant cases.

In *Crane v. Cedar Rapids & Iowa City Ry. Co.*, 395 U.S. 164 (1969), this Court reviewed a decision of the Supreme Court of Iowa on the question of whether the Federal Safety Appliance Act provision withdrawing the defenses of contributory negligence and assumption of the risk was applicable in a state-created claim by a nonemployee of the defendant railroad. The petitioner had sued in state court, alleging injuries resulting from a violation of the Safety Appliance Act through maintenance by the defendant of a

freight car with a defective coupler. On *certiorari*, the petitioner argued that the Iowa trial court had erroneously submitted to the jury the issue of contributory negligence. This Court ruled that state law must control the availability of affirmative defenses under state causes of action.

No party in *Crane* invoked original federal jurisdiction. Neither did this Court directly address whether the alleged federal violation was a "necessary element" of Crane's state claim or under what circumstances such a holding might support federal jurisdiction. Purely as dictum, the Court noted: "In contrast, the nonemployee must look for his remedy to a common law action in tort, which is to say that he must sue in a state court, in the absence of diversity, to implement a state cause of action." 395 U.S. at 166 (citations omitted). This dictum simply does not address the second alternative basis for federal jurisdiction noted in *Franchise Tax Board*. It applied the Holmes test as a principle of exclusion.

**E. Lower federal courts have often failed to distinguish state claims which merely pose factual controversies governed by settled federal law from those which will require construction and interpretation of federal statutes.**

As *Jacobson v. New York, N. H. & H. R. Co.*, 206 F.2d 153 (1st Cir.), *cert granted*, 346 U.S. 895 (1953), *aff'd per curiam*, 347 U.S. 909 (1954), illustrates, the simplicity of the Holmes test for federal question jurisdiction has made it difficult for the lower federal courts to abandon it as an exclusionary rule. Procedurally, orders of the district courts applying the Holmes test and ordering remand of removed cases have evaded review, since such remands by district courts prior to final judgment are not appealable. 28 U.S.C. § 1447(d). However, orders by courts of appeals directing remand to state court are subject to review. *Grubbs v. General Electric Credit Corp.*, 405 U.S. 699 (1972). The lower federal courts have widely displayed reluctance to accept a test of

federal question jurisdiction which is broader than Justice Holmes' maxim that "a suit arises under the law that creates the cause of action." They have demonstrated this reluctance in sometimes strained attempts to minimize the federal element of a plaintiff's state-created cause of action.

An often cited (and often misapplied) case on this issue is the decision of the Tenth Circuit in *Andersen v. Bingham & G. Ry. Co.*, 169 F.2d 328 (10th Cir. 1948). The plaintiff in *Andersen* sought damages for personal injuries sustained in an auto-train collision. He alleged ten separate grounds of negligence, including a violation of a single provision of the Safety Appliance Act, 45 U.S.C. § 1, in that the defendant operated its train in interstate commerce with defective brakes. The circuit court in *Andersen* first accurately recalled the general test of federal question jurisdiction:

In order for a suit to be one arising under the laws of the United States within the meaning of the removal statute, it must really and substantially involve a *dispute or controversy in respect of the validity, construction, or effect* of such laws, upon the determination of which the result depends. A right or immunity created by the laws of the United States must be an essential element of the plaintiff's cause of action, and the right or immunity must be such that it will be supported if one construction or effect is given to the laws of the United States and will be defeated if another construction or effect is given. . . .

*Id.* at 329-30 (emphasis added).

The court then addressed the fact that the plaintiff had invoked a violation of the federal act as a basis for liability:

The allegations in the complaint charging as an element of negligence failure on the part of the defendant to comply with the exactions of the Safety Appliance Act *merely tendered the issue of fact whether the train was operated without brakes being in operative condition as required by the Act. The complaint did not present any issue or controversy in respect to the validity, construc-*

tion, or effect of the Act. It did not set forth any right or immunity which would be supported if the Act be given one construction or effect and defeated if given another. While the pertinent provisions of the Act lurked in the background as creating a duty the breach of which constituted negligence, the right of action available and the incidents of such right of action sprang from the law of Utah. It did not arise under the laws of the United States.

*Id.* 330-31 (citations omitted) (emphasis added).

The plaintiff in *Andersen* had sued under 45 U.S.C. § 1, a statute which consists of only 92 words which make it unlawful to operate a train in interstate commerce which is not equipped so that the engineer can control the train's speed without requiring brakemen to use hand brakes. The Tenth Circuit had good cause to assume that *Andersen's* claim would require no construction or interpretation of that federal statute.

This Court had, years before, expressed displeasure with attempts to "interpret" the Safety Appliance Act to permit "equivalent" compliance as a substitute for its clear and literal meaning. *St. Louis Iron Mountain and Southern Ry. v. Taylor*, 210 U.S. 281 (1908); *Saint Joseph & Grand Island Ry. Co. v. Moore*, 243 U.S. 311 (1917). Accordingly, the precedents against anything but a literal reading of the Act supported the conclusion of the Tenth Circuit in *Anderson* that only fact questions would be presented.<sup>8</sup> The brake statute could be read to the jury verbatim and be readily understood by a juror of ordinary intelligence.<sup>9</sup> For this

<sup>8</sup> It is significant that *Moore*, *Crane* and *Jacobson*, as well as *Andersen* and *Owens v. New York Central R.R. Co.*, 267 F.Supp. 252 (E.D.ILL. 1967), discussed below, all concerned the relatively simple provisions of the Safety Appliance Act.

<sup>9</sup> The reference to "interstate commerce" in the statute is the only legal phrase contained therein. There is no indication that the status of the train as being in "interstate commerce" was at issue in *Andersen*.

reason, the court reasonably concluded that no federal legal controversy would be presented.

The circuit court in *Andersen* logically distinguished between a federal legal controversy and a factual controversy to which settled federal law must be applied. Nonetheless, *Andersen* has often been cited seemingly for the proposition that no allegation of a violation of any federal law poses anything more than a factual question for the jury. This is a much broader rule of law than that propounded by the Tenth Circuit in *Andersen* and one which has been applied to quite dissimilar federal statutes.

In *Boncek v. Pennsylvania Ry. Co.*, 105 F. Supp. 700 (D.N.J. 1952), the district court considered a claim by certain individuals for damages resulting from an explosion. The fifth count of the complaint alleged the negligence of defendants in manufacturing, packing, handling and transporting explosives contrary to applicable statutes of the United States, the State of New Jersey and the city of South Amboy, New Jersey. While acknowledging the potential federal element of one claim of negligence, the court noted:

But no recovery is sought under and by virtue of the terms of any federal statutes or regulations. The right of action for breach of such duty (if we assume that Congress by such statutes and regulations prescribed absolute duties and created correlative rights in favor of injured persons) was created by and enforceable under the laws of the state of New Jersey, and does not really and substantially involve a controversy respecting the validity or construction of a law of the United States upon the determination of which the result depends.

*Id.* at 706. The court then cited to *Andersen* and to its "issue of fact" conclusion. The federal regulations governing explosives were not even specifically cited or discussed in the opinion. The Court in *Boncek* did not consider whether an adjudication of the plaintiff's fifth count of negligence might

require a *construction or interpretation* of the federal laws governing handling of explosives. The result in *Andersen* was applied, but its rationale left behind.

In *Owens v. New York Central R.R. Co.*, 267 F. Supp. 252 (E.D. Ill. 1967), the district court remanded a claim which, in two counts, alleged injury resulting from a violation of the Safety Appliance Act, in particular, 45 U.S.C. § 2. This statute was even simpler in its language than the power brake requirement at issue in *Andersen*. It required automatic couplers on railroad cars. The district court in *Owens* again relied upon *Andersen* for the proposition that *no construction* of the federal statute was required.

The court in *Owens* also relied upon the case of *Dennis v. Southeastern Aviation, Inc.*, 176 F. Supp. 542 (E.D. Tenn. 1959). The court in *Dennis* remanded a removed case which had alleged wrongful death in a plane crash resulting from violations of regulations promulgated under the Federal Civil Aeronautics Act. Without discussing the substance of the Civil Aeronautics rules, the *Dennis* court announced:

*No question appears as to the interpretation of the rules, the only question being one of fact whether they were violated.*

\* \* \*

Bearing in mind that the allegation as to violation of the federal regulation simply tendered another issue of negligence, and involved no question of the validity or interpretation of the regulation, and bearing in mind further that all doubts should be resolved in favor of remand [citations omitted] the court is of the opinion that remand should be granted.

*Id.* at 543-44 (emphasis added). The district court in *Boncek* did not explain its observation that no need was presented for interpretation of the Civil Aeronautics rules. Perhaps the rules which the complaint put in issue were as simple and noncontroversial as those in *Andersen*. However, this does not

imply that *any* alleged federal violation can be submitted to a jury without the need for an interpretation of the statute by the court.

**F. The legal fiction that a negligence claim premised on a federal statutory violation always poses only factual questions should be discarded in those rare cases where the complaint shows the necessity for construction and interpretation of federal law.**

The *Andersen* case, which concerned a simple and noncontroversial federal statute which (as this Court had ruled) left no room for construction or interpretation, has been progressively applied to more and more complicated statutes and regulations on the never-reexamined assumption that such federal laws would pose no necessity for construction or interpretation by a federal court, but only fact questions. Over the years, the fundamental premise of *Andersen*, that the railroad brake law (the only statute there in issue) did not require interpretation or construction, has been forgotten. *Andersen* and its progeny have come to stand for the proposition that no allegation of negligence based upon violation of federal law can support federal jurisdiction. This is illustrated in the case of *Zieg v. Shearson/American Express Inc.*, 592 F. Supp. 612 (E.D. Va. 1984), a case relied upon by the Sixth Circuit in ordering remand of the Respondents' cases.

In *Zieg*, the plaintiffs alleged negligence of a commodities broker, asserting that violation of the Commodities Exchange Act constituted negligence *per se*. The Virginia district court nodded to this federal aspect of the plaintiffs' claims only in passing, stating: "A state law negligence cause of action that incorporates federal law by reference does not 'arise under' federal law. See, e.g., *Owens v. New York Central R. Co.*, 267 F. Supp. 252 (Ill. 1967); 13 Wright Miller & Cooper § 3562 at 411-412 (1975)." 592 F. Supp. at 614. *Owens* had concerned a 59-word federal statute requiring

automatic couplers in simple English. The *Owens* premise, that the federal statute there in issue posed no need for interpretation, was applied, without discussion, to a case alleging violations of the Commodities Exchange Act.

As in *Dennis*, the precise nature of the claimed federal violation is not disclosed in the *Zieg* opinion. However, the Court's assumption that the jury could be instructed on the requirements of the Commodities Exchange Act without the necessity of legal interpretation by the Court (if the *Zieg* Court even considered the *Owens* rationale) seems rash. Sometimes, though perhaps rarely, a complaint alleging negligence by violation of a federal statute shows that legal construction and interpretation of such a federal statute will be necessary. As noted above, Respondents' complaints pose such necessity.

**G. The alleged federal law violations are not tangential or potential issues but will assume prominence in the trial of Respondents' claims**

**1. Though they minimized such claims in seeking remand, Respondents did seek a private recovery for Food, Drug and Cosmetic Act violations.**

Both courts below focused on the "presumption of negligence" allegation of Respondents' Fourth Cause of Action, assuming that this was the only nexus between the claimed federal violation and Respondents' claims. However, if the "presumption" paragraph be stricken, a different picture emerges. The Fourth Cause of Action still alleges injuries proximately caused by the claimed violations, i.e., a *private cause of action*. Likewise, the Fifth Cause of Action alleges, *inter alia*, injuries proximately caused by Petitioner's failure "to submit all relevant data bearing on the safety of the drug Bendectin to the Food and Drug Administration, as required by law." J.A. 24, 33. This alleged misdeed is distinct from the

"misbranding" alleged in the previous cause of action. These claims have not been disposed of by either court. By contrast, the district court in *Griffin v. O'Neal, Jones & Feldman, Inc.*, 604 F. Supp. 717 (S.D. Ohio 1985), the *subsequent* local decision which ruled private Food, Drug and Cosmetic Act claims unavailable, ordered the Food, Drug and Cosmetic Act claim in that case stricken from the complaint. *Id.* at 720.

Respondents' private claims under the Food, Drug and Cosmetic Act, are (as they now concede) legally insufficient, but not insubstantial in a jurisdictional sense. No decision of this Court forecloses them. The possibility that they might fail to state a claim upon which relief can be granted is not a jurisdictional impediment unless they are "clearly . . . immaterial and made solely for the purpose of obtaining jurisdiction." *Mt. Healthy City Board of Education v. Doyle*, 429 U.S. 273, 278 (1976). If they fail to state a claim upon which relief can be granted, they must be dismissed *on their merits*. In *Bell v. Hood*, 327 U.S. 678 (1946), this Court stated:

Jurisdiction, therefore, is not defeated as respondents seem to contend, by the possibility that the averments might fail to state a cause of action on which petitioners could actually recover. For it is well settled that the failure to state a proper cause of action calls for a judgment on the merits and not for a dismissal for want of jurisdiction. Whether the complaint states a cause of action on which relief could be granted is a question of law and just as issues of fact it must be decided after and not before the court has assumed jurisdiction over the controversy. If the court does later exercise its jurisdiction to determine that the allegations in the complaint do not state a ground for relief, then dismissal of the case would be on the merits not for want of jurisdiction. *Swafford v. Templeton*, 185 U.S. 487, 493, 494; *Binderup v. Pathe Exchange*, 263 U.S. 291, 305-308.

*Id.* at 682.

Respondents' self-serving impeachment of their federal claims (though without withdrawing them) in seeking remand, does not change the jurisdictional fact that they were pled.

No judgment prevents Respondents from pressing their private Food, Drug and Cosmetic Act claims in state court if these actions are remanded. The District Court had jurisdiction to strike such claims, as it did in *Griffin*, but bypassed the necessity of doing so by its *forum non conveniens* dismissal. While such claims remain unstricken, the jurisdiction which they confer likewise remains.

2. Respondents will rely upon the alleged Food, Drug and Cosmetic Act violations to prove negligence *per se* and that Bendectin was a "defective product."

In arguing for remand, Respondents stated that their claims on the alleged Food, Drug and Cosmetic Act violations constituted negligence *per se*, i.e., negligence as a matter of law, under Ohio law. Such a legal contention, if adopted, would remove any issue of due care from the Fourth Cause of Action, further explaining why it was separately pled. Respondents also asserted that the claimed federal violations were probative on the question whether Bendectin was a "defective product," a central issue of their *Second* and *Third* Cause of Action. J.A. 19-21, 29-30.

For the foregoing reasons, the claimed federal law violations are not "lurking in the background" of Respondents' suits, but will have a major importance in the trial of their claims.

## II. WHERE A CLAIM WHICH "NECESSARILY DEPENDS" ON RESOLUTION OF AN ISSUE OF FEDERAL LAW IS JOINED WITH OTHER CLAIMS NOT BASED ON FEDERAL LAW WHICH WOULD, IF PLAINTIFF PREVAILS, OBVIATE THE FEDERAL QUESTION, THE PENDENCY OF SUCH LOCAL CLAIMS DOES NOT DEPRIVE THE DISTRICT COURT OF JURISDICTION.

- A. The District Court correctly ruled that the essential federal question of Respondents' Fourth Cause of Action conferred jurisdiction, notwithstanding the fact that Respondents might alternatively recover on their other, non-federal claims.

Respondents' complaints show that they also claim rights of recovery wholly apart from the violations of federal law which they allege in their Fourth Cause of Action. The District Court made no mention of this undisputed fact, focusing on the essential element of the Fourth Cause of Action. The relationship of the Fourth Cause of Action to the rest of the complaint and, in particular, to the First Cause of Action, prompted the Court of Appeals to reverse the District Court, concluding that subject matter jurisdiction was lacking. Accordingly, an appreciation of the complaint and the interrelationship of its various parts is necessary.

Respondents allege that the drug Bendectin caused their childrens' birth defects. The alleged bases for liability are several. The First Cause of Action asserts the negligence of the Petitioner "in developing, marketing, producing, manufacturing, distributing and selling" Bendectin and "in failing to test or inadequately testing the potential birth defect producing effects" of Bendectin and "in failing to warn the users of Bendectin of the potential birth defect producing effects. . . ." J.A. 1 19, 28. Respondents' proof of their First Cause of Action would require their demonstration of the applicable standard of care and a breach of that standard. This

would be a formidable and complex task, requiring that Respondents show how a reasonable maker or seller of prescription drugs conducts its business.

Respondents' pled their Fourth Cause of Action separately because it alleges a separate legal basis for assigning fault, i.e., federal violations. Respondents' do not say what law they rely upon for their contention that the asserted violations "constitute a rebuttable presumption of negligence." However, this allegation means that the Respondents' *prima facie* case will be demonstrated by showing that such violation occurred and by producing some evidence that it caused their injuries. They may dispense with proving the standard of care for a reasonable drug manufacturer or proving that the Petitioner violated that standard. Their concession that the presumption is "rebuttable" would seemingly allow Petitioner to demonstrate that it exercised due care, whether or not it had committed a violation of law. However, the burden of going forward with proof concerning due care would be shifted from the plaintiff to the defendant.

The Respondents' Fourth Cause of Action is distinct from their First because the culpable act which they undertake to prove is different. This is why their First Cause of Action alleges that the defendant's "negligence" caused the Respondents' injuries, J.A. 19, 29, ¶¶ 9, 10, while their Fourth Cause of Action, asserts that "defendant's violation of said federal statutes" caused such injuries. J.A. 22, 32, ¶ 27. Respondents' Fourth Cause of Action is premised, not on the quality of Petitioner's acts or omissions as *negligent*, but on their character as unlawful as a *federal matter*. Their complaint "establishes . . . that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law." *Franchise Tax Board*, 463 U.S. at 27-28.

The Court of Appeals did not dispute (or even address) the fact that the Fourth Cause of Action was dependent on this federal issue. Rather, it found that Respondents might prove "negligence" without proof of the federal violation and that

the federal violation was thus not "necessary" to Respondents' "right to relief." J.A. 10. The Court of Appeals obviously read the Fourth Cause of Action in combination with the First and treated these two counts as asserting a single "cause of action" and a single "right to relief" for negligence. *Id.* The Court of Appeals erred by applying a concept of "cause of action" and "right to relief" which was broader than that which this Court has traditionally employed in determining whether federal question jurisdiction is present. If *any* "cause of action" or *any* "right to relief" requires construction and interpretation of federal law, jurisdiction is present.

**B. The question whether a right to relief asserted in a "cause of action" is federally created or involves an essential federal issue is answered by consideration of the cause of action itself, regardless of plaintiffs' potential for recovery on non-federal grounds.**

If a plaintiff alleges a cause of action which relies on a proposition of federal law, it is irrelevant that plaintiff might achieve a recovery based on other claims which do not depend on that federal issue. This is illustrated by this Court's analysis of the complaint in *Franchise Tax Board*. That complaint consisted of two "causes of action." The first sought recovery on three tax levies issued pursuant to the California Tax Code. The second sought a declaration that the defendants were "legally obligated to honor future levies by the Board," asserting that the defendant's refusals to honor the levies were premised on the preemptive effect of The Employers Retirement Income Security Act (ERISA). 463 U.S. at 7.

This Court dealt only briefly with the first cause of action, observing that the issue of preemption by ERISA was purely defensive and that the Tax Board's cause of action itself arose solely under state law. 463 U.S. at 13. The Court then ruled out "federal question" jurisdiction under the second cause of

action, holding that resort to a declaratory judgment as a form of action could not convert an implicitly defensive issue into a necessary element of the plaintiff's affirmative case. 463 U.S. at 18-19.

The facts in *Franchise Tax Board* were susceptible to the same analysis as that which the Court of Appeals applied to the Respondents' claims. Indeed, such would have provided a more direct basis upon which to resolve the case than that which the Court employed. In *Franchise Tax Board*, this Court noted:

Appellant's complaint sets forth two "causes of action," one of which expressly refers to ERISA; *if either comes within the original jurisdiction of the federal courts, removal was proper as to the whole case.* See 28 U.S.C. § 1441(c).

463 U.S. at 13.

This pronouncement concerned two causes of action which were, in their legal theory, *duplicative*. Had the Tax Board prevailed on its first cause of action for recovery on the three tax levies, such would have mooted the second cause of action. The issue of preemption of the state tax code by ERISA would necessarily have been decided under the first cause of action, but only as an affirmative defense raised by the trustees. The first cause of action would have determined the plaintiff's *entire right to relief*. This fact was not even discussed by this Court. The "causes of action" were evaluated *separately* and regardless of the fact that the first and clearly *nonfederal* claim was sufficient to decide the whole controversy.

A similar jurisdictional evaluation was conducted by the circuit court in *Westmoreland Hospital Assoc. v. Blue Cross*, 605 F.2d 119 (3rd Cir. 1979), *cert. denied*, 444 U.S. 1077 (1980). In *Westmoreland*, several hospitals sued a health insurer in state court. The hospitals alleged breach of a contract to reimburse the hospitals for care of subscriber patients on a

complicated "cost" basis rather than at the hospitals' standard rates. The plaintiffs claimed that Blue Cross had wrongly withheld a part of the reimbursement, in that it routinely deducted from the reimbursements certain grant payments received by them under the Community Mental Health Centers Act (42 U.S.C. § 2688 *et. seq.*). The hospitals contended that this practice violated a provision against such grants' being applied to cross-subsidize payments by insurers. *Id.* at 121-22. Defendant removed this suit to federal court.

The hospitals moved for remand, but their motion was denied. The action was tried and decided adversely to the hospitals, and, as the circuit court reports, solely on state law grounds. The hospitals again attacked jurisdiction on appeal, urging that their allegations of federal violation were not, on the face of their complaint, indispensable to their recovery. The Third Circuit held that this fact was inconsequential as to jurisdiction.

There is much force to appellants' contention that their claim for relief involved only the interpretation of the Blue Cross contract under Pennsylvania law. Certainly, this was the theory on which the law suit was ultimately decided. But our inquiry as to the presence of federal jurisdiction is not on the basis of how a complaint *could* have been structured or of what theory was eventually relied upon at trial. [Emphasis in original].

\* \* \*

Notwithstanding their contention that it would have been possible to decide the contract dispute solely on state law precepts, we see that appellants gratuitously volunteered on the face of their complaint legal conclusions based on federal statutes and regulations. Although these allegations may have been unnecessary for the ultimate disposition of the case, and here we are accepting the appellants' premise, surplusage of federal claims in pleadings is not the test.

\* \* \*

To accept their contention would require us to evaluate the question of federal jurisdiction at the time of trial in the federal court and to decide that subject matter jurisdiction did not obtain because appellants went to trial on state law theories only. To do so would be to ignore the rule in removal cases that subject matter jurisdiction is to be determined from the face of the complaint and on the basis of the record in the state court, *at the time the petition for removal is presented*. [Emphasis in original]. The hospitals' complaint, so viewed, *reveals alternative bases for relief against Blue Cross, namely, that the hospitals were entitled to relief under the contract whether it was interpreted according to state law principles or under the federal mental health statutes*. Because appellants' complaint was based in part on federal statutes, and federal agency regulations and interpretations, we conclude that there was jurisdiction under 28 U.S.C. § 1331(a).

605 F.2d at 123-124 (emphasis added).

No plaintiff is ever bound to pursue a federal contention relied upon in his complaint. Liberal amendments to pleadings are the rule in federal court, Fed. R. Civ. P. 15, and the trial court must grant appropriate relief even if it is not requested in the complaint. Fed. R. Civ. P. 54(c). Still, complaints are evaluated for subject matter jurisdiction based on the assumption that the plaintiff intends to try all the "causes of action" which he pleads. Rule 8(e)(2) of the Federal Rules of Civil Procedure provides: "When two or more statements [of a claim] are made in the alternative and one of them, if made independently would be sufficient, the pleading is not made insufficient by the insufficiency of one or more of the alternative statements." The same rule must apply to the jurisdictional sufficiency of a claim upon which federal question jurisdiction depends. In holding, in *Franchise Tax Board*, that jurisdiction is present where a plaintiff's "right to relief" necessarily depends on a federal question, this Court

did not require that the plaintiff seek relief *solely* on federal grounds, or that *all* his "causes of action" be based on federal law.

The phrase "cause of action" has meant different things in different situations. *United Mine Workers v. Gibbs*, 383 U.S. 715, 722-724 (1966). In discussing the plaintiff's "causes of action" in *Franchise Tax Board*, this Court used such term in a narrower sense than that applied in other contexts. In more traditional parlance, the doctrine of *res judicata* is also known as the rule against splitting a "cause of action." This was the sense in which this Court used the term in *Baltimore S.S. Co. v. Phillips*, 274 U.S. 316 (1927), ruling that a seaman who had brought and lost a suit for negligence could not begin a new suit against the same defendant. He was precluded from a new suit on the same "cause of action", though the facts he alleged might be different. *Id.* at 321.

In *Hurn v. Oursler*, 289 U.S. 238 (1933), this Court defined the limits of pendent jurisdiction in terms of the power of a federal court to decide an entire "cause of action," again meaning all the legal bases for recovery for a single wrong, including those based on state *and* federal law. Against that analytical framework, a "cause of action" was subject to federal jurisdiction if *any* of the theories of recovery necessitated a decision on a substantial federal question. This was clearly not the sense in which this Court used "cause of action" in analyzing the *Franchise Tax Board* complaint.

Respondents' "cause of action," *in the sense of their general right to recover for the injuries which they assert*, does not "necessarily depend" on a disputed question of federal law. They could, theoretically, prove negligence without resort to the presumption of negligence based upon the alleged Food, Drug and Cosmetic Act violations. Likewise, they might prove a case for strict liability in tort or breach of express or implied warranties without introducing proof of the alleged violations. However, this is not the test of federal jurisdiction under 28 U.S.C. § 1331, even as to *federally created* "causes of action."

The Sixth Circuit relied upon *Franchise Tax Board* for the proposition that federal question jurisdiction would lie where "a well-pleaded complaint establishes . . . that federal law creates the cause of action . . . ." J.A. 9. To say that federal law "creates the cause of action" does not require a finding that the plaintiff would have no lawsuit but for the federal statute upon which he sues. A plaintiff invoking federal question jurisdiction often joins in his complaint state and federal claims each of which seek the same relief for the same actionable wrong. For example, in *United Mine Workers v. Gibbs*, 383 U.S. 715 (1966), the plaintiff premised federal jurisdiction on an allegation of a secondary boycott under section 303 of the Labor Management Relations Act and on the common law of Tennessee.

Measured by the definition of "cause of action" in *Baltimore SS Co. v. Phillips* and *Hurn v. Oursler*, Gibbs' complaint did not show that federal law "created" his "cause of action." Gibbs' overall "right to relief" did not "necessarily depend" on his federal labor law claim. In fact, the federal claim upon which Gibbs invoked jurisdiction was eventually found to be legally insufficient. Tennessee state law supplied the *only* right to recovery.

As illustrated in *Gibbs*, to say that federal law "creates the cause of action" does not imply that a plaintiff must have no "right to relief" apart from that granted by the federal statute. A plaintiff may often have more than one "right to relief," and more than "one cause of action" in that he has one or more state *and* federal grounds for his claim. The same concept of "cause of action" and "right to relief" applies to the alternate basis for federal jurisdiction as noted in *Franchise Tax Board*.

The Court of Appeals read *Franchise Tax Board* to preclude federal jurisdiction because the Respondents' complaint included *another* "cause of action" for negligence, one without reference to federal law. The Court of Appeals was apparently untroubled by the fact that the Respondents

might also recover on strict liability or breach of warranty without any reference to negligence. It saw the First and Fourth Causes of Action in the Respondents' complaints as alleging a single "right to relief." This was based upon the use of the word "negligence" in each such claim. While the Respondents' First and Fourth Causes of Action each include the word "negligence," the differences between these two claims outweigh their similarities.

The Respondents contend that violation of a *specific* safety statute resulting in injury to a member of the class which the statute is designed to protect constitutes negligence *per se*, i.e., negligence as a matter of law, in Ohio. By this standard, such a violation is more than grounds for a presumption of negligence but constitutes a civil wrong in itself to which Petitioner's proof of due care would be deemed irrelevant. If this view of Ohio law were applied,<sup>10</sup> the separate and distinct character of the Fourth Cause of Action is all the more apparent. Respondents' Fourth Cause of Action asserts a separate and distinct "right to relief" which necessarily depends on their proof of a violation of the Food, Drug and Cosmetic Act. The District Court correctly found jurisdiction on this basis.

As a member of the pharmaceutical industry, Merrell Dow Pharmaceuticals Inc. is governed by the Food, Drug and Cosmetic Act and the comprehensive regulations promulgated thereunder as administered by the Food and Drug Administration. The appropriate analysis of Respondents' claims that Petitioner violated this regulatory scheme thus requires construction and interpretation of federal statutes and administrative regulations. This is in sharp contrast to most negligence complaints which, although they may allege violations of statutes, do not actually require the construction and interpretation of federal statutes.

<sup>10</sup> Petitioner has and does dispute that Ohio law would ever apply in these actions. J.A. 50.

The Respondents were not obliged to rely upon federal law in their complaints. Had they refrained from doing so, or had they renounced that reliance when seeking remand, their cases would not now be before this Court. The risk that plaintiffs will contrive federal jurisdiction by far-fetched allegations is not a new problem but one with which the district courts routinely and effectively deal. Petitioner cannot be accused of contriving removal jurisdiction in the instant cases, since it offered to accept remand if Respondents would abandon the novel federal propositions upon which their Fourth Causes of Action were based. J.A. 52-54. Having cloaked the extraterritorial element of their accusations of "misbranding" in inaccurate factual allegations (after first alleging that Petitioner violated the Food, Drug and Cosmetic Act as it applies to drugs manufactured and sold in the U.S.), the Respondents would not desist, even to achieve remand.

It is not the office of the federal courts to oversee the routine application of settled federal law to state-created claims. Here the direct enforcement of the involved complex regulatory statute has been delegated by Congress solely to an administrative agency with the appropriate special expertise. 21 U.S.C. § 337. Moreover, the Respondents seek to break new ground by "exporting" federal law to other countries and "importing" foreign tort claims for trial in state court, based on the extraterritorial operation of such federal law.

Under the Respondents' view of federal jurisdiction, involved state courts may determine individually, in each case before them, whether Petitioner violated the Food, Drug and Cosmetic Act as to Bendectin, Debendox or Canadian Bendectin. Each such case may progress at its own pace through each state's court system with the only avenue for imposing uniformity of federal interpretation being the jurisdiction, on *certiorari*, of this Court. Such cases will require not only the application but the development of federal law in a context for which the statute (as Respondents vigorously point out) was not designed, i.e., private enforcement.

As this case dramatically illustrates, because of the federal precedents on *forum non conveniens*, the state forum will be most attractive to foreign plaintiffs whose claim as intended beneficiaries of the statute is most tenuous. Decisions which sustain such foreign plaintiffs' credentials as members of the "protected class" will only enhance the attractiveness of an American forum to such foreign citizens. In such a situation, the federal question of a foreign citizen's complaint is one of great significance.

The complaints of the Respondents pose substantial federal questions upon which their Fourth Causes of Action are unavoidably dependent. Their cases arise under federal law and this Court is respectfully urged to so rule.

### CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals should be reversed and the judgment of the District Court reinstated by this Court without modification.

Respectfully submitted,

Frank C. Woodside III  
2100 Fountain Square Plaza  
511 Walnut Street  
Cincinnati, Ohio 45202  
(513) 977-8200

Counsel for Petitioner

Of Counsel:

John E. Schlosser  
Christine L. McBroom  
DINSMORE & SHOHL  
2100 Fountain Square Plaza  
511 Walnut Street  
Cincinnati, Ohio 45202

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IN THE  
**Supreme Court of the United States**  
OCTOBER TERM, 1985

MERRELL DOW PHARMACEUTICALS, INC.,  
*Petitioner,*

v.

LARRY JAMES CHRISTOPHER THOMPSON and DONNA  
LYNN THOMPSON as Next Friends and Guardians of  
JESSICA ELIZABETH THOMPSON, LARRY JAMES CHRIST-  
OPHER THOMPSON, Individually, and DONNA LYNN  
THOMPSON, Individually, *et al.*,  
*Respondents.*

**BRIEF FOR RESPONDENTS**

STANLEY M. CHESLEY  
WAITE, SCHNEIDER, BAYLESS & CHESLEY  
1513 Central Trust Tower  
Fourth and Vine Streets  
Cincinnati, Ohio 45202  
(513) 621-0267

*Counsel for Respondents*

*Of Counsel:*

ALLEN T. EATON

ALLEN T. EATON & ASSOCIATES  
1029 Vermont Avenue, N.W.  
Washington, D.C. 20005

FELICIA C. SMITH

LAW OFFICES OF GEORGE A. KOKUS  
1521 N.W. 15th Street Road  
Miami, Florida 33125

PRESS OF BYRON S. ADAMS, WASHINGTON, D.C. (202) 347-8203

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## QUESTIONS PRESENTED

1. Where a complaint founded on traditional theories of tort liability alleges that the defendant violated specific provisions of the Federal Food, Drug and Cosmetic Act and that the violation of the federal statute constitutes a rebuttable presumption of negligence, do such allegations arise under federal law so as to confer removal of jurisdiction on the district court?

2. Where a private litigant seeks a monetary remedy on the theory of negligence and alleges, *inter alia*, that a drug manufacturer violated provisions of the Federal Food, Drug and Cosmetic Act, do the allegations create a federal interest sufficient to require resolution by a federal court?

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IN THE  
Supreme Court of the United States

OCTOBER TERM, 1985

No. 85-619

MERRELL DOW PHARMACEUTICALS, INC.,  
*Petitioner,*

vs.

LARRY JAMES CHRISTOPHER THOMPSON AND DONNA LYNN  
THOMPSON, AS NEXT FRIENDS AND GUARDIANS OF JESSICA  
ELIZABETH THOMPSON, LARRY JAMES CHRISTOPHER  
THOMPSON, INDIVIDUALLY, AND DONNA LYNN THOMPSON,  
INDIVIDUALLY, *et al.*,  
*Respondents.*

On Writ of Certiorari to the  
United States Court of Appeals for the  
Sixth Circuit

## BRIEF FOR RESPONDENTS

## STATEMENT OF THE CASE

Petitioner Merrell Dow Pharmaceuticals, Inc. (formerly known as Richardson-Merrell, Inc.) is a pharmaceutical manufacturer incorporated in Delaware with its principal place of business in Hamilton County, Ohio. The Respondents, Larry James Christopher Thompson and Donna Lynn Thompson, are Canadian citizens residing in Napanee, Ontario. The Respondents, Neil Frazier Mac-

Tavish and Margaret MacTavish, are British subjects residing in Linlithgow, Scotland. J.A. 17-18, 27-28.

The Thompsons and MacTavishs filed separate lawsuits against the Petitioner in the Court of Common Pleas, Hamilton County, Ohio, on September 1, 1983. They sued the Petitioner individually and as next friends and guardians of their minor children, Jessica Elizabeth Thompson and Neil MacTavish, respectively. The complaints in both actions virtually are identical with minor variations that are not pertinent to the instant appeal. Each complaint alleges that the minor child was born with multiple deformities as a result of the mother's ingestion of Bendectin, a drug product developed, tested, produced, manufactured and sold by Petitioner for the relief of nausea during pregnancy. J.A. 18, 28.

The allegations in each complaint are based on state-created theories of common law liability and grouped under six causes of action. The first three causes of action and the fifth and sixth causes of action, respectively, allege negligence, breach of warranties, strict liability in tort, common law fraud, and gross negligence. The fourth cause of action alleges that Petitioner violated specific reporting and labeling provisions of the Federal Food, Drug and Cosmetic Act (hereinafter FDCA), 21 U.S.C. § 301, *et seq.* (52 Stat. 1040), and that the violation of the federal statute in the promotion of Bendectin "constitutes a rebuttal presumption of negligence." J.A. 21-22, 31-32.

On September 8, 1983, Petitioner removed the cases from the Court of Common Pleas, pursuant to 28 U.S.C. § 1332 and 28 U.S.C. § 1441, on the grounds that the actions are "between citizens of a state and citizens or subjects of a foreign state, and [are] founded, in part, on an alleged claim arising under the laws of the United States." J.A. 36-37, 39-40.

On October 14, 1983, the Thompsons and MacTavishs filed a joint motion to remand under § 1447(c) and a memorandum in support thereof, J.A. 42-48. They noted that the Petitioner is a citizen of Ohio and, therefore, pursuant

to 28 U.S.C. § 1441(b), diversity of citizenship does not provide a basis for removal of the actions. J.A. 47. Addressing Petitioner's assertion that the actions arise under federal law, Respondents stated, in part:

In asking the Court to recognize the Food, Drug and Cosmetic Act as establishing the standard of care required of a drug manufacturer, federal jurisdiction is not vested in this Court under 28 U.S.C. § 1331. In the instant case, unlike *Cort v. Ash*, 422 U.S. 66 (1975) (private right of action principles set forth by Court), plaintiffs do not assert a federal statute as the jurisdictional basis for their claims, nor do they assert that their claims arise under the federal Food, Drug and Cosmetic Act.

\* \* \*

Plaintiff's actions, to be sure, do not arise under federal law, as they do not assert a federally-created cause of action. Plaintiffs only urge that the federal Food, Drug and Cosmetic Act embodies the appropriate *standard of care* to be employed by the Ohio Court in determining if Merrell has been negligent, or if Bendectin is a defective product.

J.A. 45-46.

Although the Thompsons and MacTavishs filed a joint motion to remand, they failed to include specific facts peculiar to the Thompsons in their memorandum in support of the motion. Under the heading, "Operative Facts," they state the following:

Plaintiffs are residents of Scotland, United Kingdom, who allege that their children suffered birth defects as the result of ingestion of Debendox during pregnancy. Debendox is the British trade

name for the antinauseant morning sickness drug Bendectin manufactured by defendant Merrell.

...

J.A. 43.

The above statement pertains only to the MacTavishs. The Thompsons are citizens of Canada. The Canadian trade name for the drug product ingested by Donna Lynn Thompson is Bendectin. In their complaints, the Thompsons and MacTavishs refer to the drug product allegedly ingested as Bendectin. In fact, the trade name for the drug product ingested by Margaret MacTavish is Debendox. Respondents contend that Petitioner either developed, tested, promoted and/or manufactured the drug products ingested (both "Canadian" Bendectin and Debendox) in Hamilton County, Ohio, or directed these activities from Hamilton County, Ohio. Whether or not Petitioner performed or directed any or all of these activities is a factual dispute between the parties and is not properly before this Court in its consideration of the jurisdictional issue.

On October 31, 1983, Petitioner filed a memorandum in response to Respondents' motion to remand. J.A. 49-56. Petitioner stated, in part:

If Plaintiffs do not intend on litigating the issues concerning allegations that Merrell Dow violated the reporting requirements of the federal Food, Drug and Cosmetic Act in a state court action, then Merrell Dow concedes that, although clear from the face of the Complaints, no federal question jurisdiction exists in these cases.

\*\*\*

Although Plaintiffs state that they are not suing to *enforce* the provisions of the federal Food, Drug and Cosmetic Act, they allege, nevertheless, that Merrell Dow *violated* provisions of the Act. "A suit may arise under federal law, even though a federal remedy is not sought, if the plaintiff's claim relies substantially on proposi-

tions that define federal rights, duties or relationships." *Guinasso v. Pacific First Federal Savings and Loan Assn.*, 656 F.2d 1364, 1367 n. 7 (9th Cir. 1981).

Based upon the foregoing citations of authority and upon Merrell Dow's suspicion that Plaintiffs will attempt to raise the alleged violations of a federal statute in the state court if the actions are remanded, it is submitted that this cause of action "arises under" the laws of the United States. ...

J.A. 53, 55 (emphasis in original).

Respondents replied to Petitioner's memorandum in response on November 22, 1983. J.A. 57-60. They argued, in part, as follows:

The defendant is an Ohio corporation and the rights claimed are those of parents and children who seek redress under the common law for injuries sustained from the ingestion of defendant's drug product Bendectin (Debendox). The foundation of plaintiffs' lawsuit turns upon duties and responsibilities imposed upon defendant under the laws of negligence, strict liability, fraud and implied and express warranty.

\*\*\*

The mere reference to a federal statute as a criterion or test, when the law of the United States has no force of its own, does not suffice to establish that a cause of action arises under the laws of the United States. *Moore v. Chesapeake & Ohio Ry.*, 291 U.S. 205 (1934). ...

\*\*\*

The validity, construction and/or effect of the Food, Drug and Cosmetic Act are *not* "pivotal" issues in this case; ...

\* \* \*

Moreover, plaintiffs' assertions that defendant has violated the Food, Drug and Cosmetic Act also can be viewed as merely replies in anticipation that defendant will raise as defenses its compliance with the provisions of the Act and the subsequent approval of the Food and Drug Administration for the marketing of Bendectin. Again, a federal question is not embraced in this instance. *Phillips Petroleum Co. v. Texaco, Inc.*, 415 U.S. 125, 127-28 (1974).

J.A. 57-59 (emphasis in original).

While Respondents' motion to remand was pending, Petitioner moved to dismiss Respondents' actions on the ground of *forum non conveniens*. In one opinion, filed May 14, 1984, the District Court denied Respondents' motion to remand and granted Petitioner's motion to dismiss the case on the ground of *forum non conveniens*. J.A. 13-16. In its consideration of the jurisdictional issue, the district court noted that "[i]n attempting to clarify the phrase 'arising under,' the Supreme Court has formulated definitions employing varying language. . . ." (citations omitted). J.A. 14-15. By way of a footnote, the district court stated that Respondents' cases are analagous to *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921), and distinguishable from *Moore v. Chesapeake & Ohio Ry.*, 291 U.S. 205 (1934). J.A. 15 n. 3. On that premise, the District Court applied the general rule set forth in *Smith* to Respondents' fourth causes of action. The district court stated:

Phrased in terms of the *Smith* standard, plaintiffs' "right to relief depends upon the . . . application of the . . . laws of the United States." *Smith, supra*, at 199. Accordingly, the Court holds that plaintiffs' fourth cause of action arises

under the laws of the United States and that these cases were properly removed . . . .

J.A. 15-16.

On appeal, Respondents argued only the jurisdictional issue. The court of appeals reversed the judgment of the district court on jurisdictional grounds and remanded Respondents' action to the district court with instructions to remand the actions to state court. J.A. 8-10. The court of appeals stated:

The standard for determining when an action is removable is whether the court would have had jurisdiction, subject to the limitations of § 1441(b), if the action had been instituted originally in federal court under 28 U.S.A. [sic] §1331 or § 1332. See *Franchise Tax Board v. Construction Laborers Vacation Trust*, 103 S.Ct. 2841, 2845 (1983). Consequently, a case removed to federal court under the guise of federal question jurisdiction presents a federal question when it "arises under" federal law. In *Franchise Tax Board*, the Court stated:

Under our interpretations, Congress has given the lower courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a well pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law.

*Id.* at 2856 [463 U.S. at 27-28].

The parties agree that the FDCA does not create or imply a private right of action for individuals injured as a result of violations of the Act. Federal question jurisdiction would, thus, exist only if plaintiffs' right to relief depended necessarily on a substantial question of federal law. Plaintiffs' causes of action referred to the FDCA merely as

one available criterion for determining whether Merrell Dow was negligent. Because the jury could find negligence on the part of Merrell Dow without finding a violation of the FDCA, the plaintiffs' causes of action did not depend necessarily upon a question of federal law. Consequently, the causes of action did not arise under federal law and, therefore, were improperly removed to federal court. See *Zeig v. Shearson/American Express, Inc.*, 592 F.Supp. 612, 613-14 (E.D.Va. 1984); *State of Florida ex rel. Broward County*, 329 F.Supp. 364, 366 n. 3 (S.D.Fla. 1971).

J.A. 9-10.

Petitioner filed a petition for a writ of *certiorari* which was granted on December 2, 1985.

### SUMMARY OF ARGUMENT

Respondents' allegations of negligence based on violation of the FDCA are not created by federal law. Federal courts that have considered claims alleging violation of the Act have uniformly refused to imply a private right of action under the Act on the basis that Congress expressly determined that a federal right of action under the Act would unnecessarily duplicate available state remedies. Moreover, Respondents' claims cannot be considered as disguised attempts to state claims directly under the Act, for Respondents specifically allege that violation of the federal statute "constitutes a rebuttable presumption of negligence." Respondents' claims are, therefore, state-created claims predicated on the theory of negligence.

The court of appeals correctly found that plaintiffs' right to relief on the theory of negligence does not necessarily depend on a substantial question of federal law. In applying the test set forth in *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983), this Court properly recognized that violation of the federal statute was merely an alternative ground on which neg-

ligence could be predicated and, therefore, Respondents could obtain relief on the theory of negligence without a finding that the statute was violated. The court of appeals' treatment of Respondents' fourth causes of action is consistent with the treatment of other courts considering the availability of federal question jurisdiction over complaints containing several separately numbered "counts," or "causes of action," founded on negligence, one of which alleges violation of a federal statute. Although the claims of negligence are alleged in separate counts or causes of action, these courts have emphasized that the gravamen of the claims is negligence and that each claim merely alleges another ground for negligence. This approach is based on practicality and necessity. Moreover, it is consistent with this Court's statements that a cause of action consists of a *right* which the facts merely show and, therefore, multiplication of the grounds of negligence alleged to have caused the same injury does not multiply the causes of action. Neither the holding nor the approach of the Court in *Franchise Tax Board* foreclose analysis of each "cause of action" in terms of its underlying legal basis which the separately alleged facts show, in order to determine the "whole" cause of action *before* applying the *Franchise Tax Board* test. In fact, in *Franchise Tax Board*, the plaintiff's action for a declaratory judgment presented federal questions on its face and the plaintiff's right to the declaration sought necessarily depended on resolution of the questions. Nonetheless, the Court analyzed the declaratory cause of action in terms of the underlying coercive action before applying its own test.

This Court has specifically held that state law negligence claims invoking federal safety statutes do not create federal question jurisdiction. *Moore v. Chesapeake & Ohio Ry.*, 291 U. S. 205 (1934). Analysis of the *Moore* opinion, in conjunction with other opinions that examine these claims, reveals that the effect of a violation of the statute in the resolution of the claim is decided by the state court on common law principles or by statute and, hence, will vary according to the jurisdiction. Moreover, these claims pre-

sent state issues bearing on a plaintiff's right to recover, such as proximate cause and contributory negligence, that predominate over any concerns over the application of a federal statute. The Court's holding in *Moore*, therefore, is based on the reality that the states' interest in resolving these claims overshadows any federal interest. It follows that the reference to a federal statute in Respondents' fourth causes of action is not sufficient to warrant primary adjudication in the federal courts. As this Court stated in *Moore*, any questions concerning the application of a federal statute that may arise may be appropriately reviewed by this Court on *certiorari*.

Respondents' allegations of negligence based on violation of the FDCA function as assertions that federal law deprives Petitioner of a defense or defenses he may raise and, therefore, do not give rise to federal question jurisdiction. The effect of violations of the FDCA in the instant case is determined by the common law of Ohio. However, if violation of the statute is negligence *per se* under Ohio law, then Respondents' allegations deprive Petitioner of any defenses to a claim of negligence under Ohio law. If, on the other hand, violation of the statute constitutes a rebuttable presumption of negligence, then Respondents' allegations foreclose the defense that negligence was not shown by a preponderance of the evidence. If violation of the statute is considered only evidence of negligence, then Respondents' allegations deprive Petitioner of the defense that it met the standard of care of the reasonable drug manufacturer.

Congress has established that the provisions of the FDCA are to be enforced publicly, and federal courts have refused to imply a private right of action under the Act. Resolution of claims involving only private litigants by a federal court, therefore, will not promote the federal scheme regulating pharmaceuticals, nor will application of provisions of the FDCA by the Ohio court to a private claim burden the United States in its enforcement of the Act. The allegations in Respondents' fourth causes of action rely on well-defined provisions that can be applied

by the Ohio court. Moreover, the foreign citizenship of Respondents raises only disputed factual issues regarding whether Petitioner developed, tested, promoted, manufactured, or sold Bendectin (Debendox) in Ohio or directed any of these activities from Ohio. Respondents' fourth causes of action simply do not create a federal interest sufficient to warrant invoking the jurisdiction of the federal court.

Finally, any finding that state law negligence claims alleging violation of a federal safety statute give rise to federal question jurisdiction will provide every plaintiff suing a party subject to federal regulation with an opportunity to invoke federal jurisdiction. Similarly, defendants regulated by federal statutes arguably would be able to remove these claims to federal court, if the plaintiff alleges that a defendant failed to follow safety precautions required under a federal statute, but does not specifically refer to the statute. In either event, there would be an untenable flood of tort litigation in the federal courts, which Respondents submit is most appropriately left to the state courts under 28 U.S.C. § 1331.

## ARGUMENT

- I. WHERE A COMPLAINT FOUNDED ON TRADITIONAL THEORIES OF TORT LIABILITY ALLEGES THAT THE DEFENDANT VIOLATED SPECIFIC PROVISIONS OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT AND THAT THE VIOLATION OF THE FEDERAL STATUTE CONSTITUTES A REBUTTABLE PRESUMPTION OF NEGLIGENCE, SUCH ALLEGATIONS DO NOT ARISE UNDER FEDERAL LAW SO AS TO CONFER REMOVAL JURISDICTION ON THE DISTRICT COURT.

**A. The Court of Appeals Correctly Found That Federal Law Does Not Create Respondents' Fourth Causes Of Action Nor Does Respondents' Right To Relief Necessarily Depend On Resolution Of A Substantial Question Of Federal Law And, Therefore, Respondents' Complaints Do Not Present A Federal Question Upon Which Removal Properly Could Be Based.**

The right of removal is a congressionally-imposed restriction on the power of a state court to determine controversies and, therefore, the removal statutes must be strictly construed. *Shamrock Oil & Gas Co. v. Sheets*, 313 U.S. 100, 108-109 (1941). If, prior to judgment, it appears that an action was improperly removed from state court, the district court must remand it to the state court. 28 U.S.C. § 1441(c); *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1, 8 (1983). When the defendant is a citizen of the state in which the action is brought, the propriety of removal depends on whether the case is within the original jurisdiction of the federal courts under 28 U.S.C. § 1331. *Id.* at 8.<sup>1</sup>

<sup>1</sup>28 U.S.C. § 1441 provides:

(a) Except as otherwise expressly provided by Act of Congress, any civil action brought in a State Court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district court of the United States for the district and division embracing the place where such action is pending.

(b) Any civil action of which the district courts have original jurisdiction founded on a claim or right arising under the Constitution, treaties or laws of the United States shall be removable without regard to the citizenship or residence of the parties. Any other such action shall be removable only if none of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought.

(c) Whenever a separate and independent claim or cause of action, which would be removable if sued upon alone, is joined with one or more otherwise non-removable claims or causes of action, the entire case may be removed and the district court may determine all issues therein, or, in its discretion, may remand all matters not otherwise within its original jurisdiction.

Section 1331 provides that "the district courts shall have orig-

In *Franchise Tax Board*, the Court cautioned that "the statutory phrase 'arising under the Constitution, laws, or treaties of the United States' has resisted all attempts to frame a single, precise definition for determining which cases fall within, and which cases fall outside, the original jurisdiction of the district courts." *Id.* at 8. However, after considering the various definitions formulated in the past, the Court set forth the following two-pronged test:

Under our interpretations, Congress has given the lower federal courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a well-pleaded complaint established either that *federal law creates the cause of action* or that *the plaintiffs' right to relief necessarily depends on resolution of a substantial question of federal law*.

*Id.* at 27-28 (emphasis added).

**1. Respondents' allegations, although invoking a federal safety statute, constitute a claim of right under Ohio law.**

The Federal Food, Drug and Cosmetic Act (FDCA) does not expressly create a private right of action, and federal courts have uniformly refused to imply a private right of action under the Act. *Pacific Trading Company v. Wilson & Co., Inc.*, 547 F.2d 367 (7th Cir. 1976); *National Women's Health Network, Inc. v. A. H. Robins, Inc.*, 545 F.Supp. 1177 (D.Mass. 1982); *Gelley v. Astra Pharmaceutical Products, Inc.*, 466 F.Supp. 182 (D.Minn. 1979), *aff'd*, 610 F.2d 558 (8th Cir. 1979); *State of Florida ex. rel. Broward County v. Eli Lilly & Co.*, 329 F.Supp. 364 (S.D.Fla. 1971); *Cross v. Board of Supervisors of San Mateo County*, 326

inal jurisdiction of all civil actions arising under the Constitution, treaties or laws of the United States." 28 U.S.C. § 1331 (1976 ed. Supp. V).

F.Supp. 634 (N.D.Cal. 1968), *aff'd*, 442 F.2d 362 (9th Cir. 1971).<sup>2</sup>

Petitioner submits, nevertheless, that Respondents' fourth causes of action are a disguised attempt to state a claim directly under the FDCA. In order to support its position, Petitioner urges that Court to ignore Respondent's specific allegation that violation of the federal statute constitutes a rebuttable presumption of negligence. Relying on *Bell v. Hood*, 327 U.S. 678 (1946), Petitioner asserts that the district court had subject matter jurisdiction to determine whether Respondents' fourth causes of action state a claim upon which relief can be granted.

Respondents' fourth causes of action are specifically predicated on a state law theory of negligence. This allegation of negligence cannot be ignored in examining the basis for their claim. The petitioners in *Bell* filed suit directly in federal district court to recover damages allegedly sustained as a result of a violation of their rights under the Fourth and Fifth Amendments. The complaint in *Bell* contained no allegations predicated on plaintiffs' claim on a common law theory of tort liability made actionable by state law.

In contrast, Respondents herein filed their actions in state court. Although they invoke a federal safety statute in their fourth causes of action, they allege that the violation of the statute gives rise to liability pursuant to the common law theory of negligence. Moreover, the FDCA does not provide a right of action to individuals injured

<sup>2</sup>Applying the standards for determining the availability of an implied right of action as set forth in *Cort v. Ash*, 422 U.S. 55 (1975), courts have examined the legislative history of the FDCA. An express provision for a private right of action for damages was included in an early version of the FDCA, but omitted from all later versions on the ground that it would create unnecessary federal action duplicative of state remedies. *National Women's Health Network, Inc. v. A. H. Robins, Inc.*, 545 F.Supp. at 1179-80; *State of Florida ex rel. Broward County*, 329 F.Supp. at 365.

as a result of violations of the Act, nor do Respondents attempt to state a claim under the Act. Federal law, therefore, does not create Respondents' fourth causes of action and Petitioner's reliance upon *Bell* is misplaced.

## 2. Respondents' right to relief does not necessarily depend on resolution of an issue of federal law.

The fact that an issue of federal law may or will emerge during the course of litigation is not sufficient to establish federal question jurisdiction. *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1, 27-28 (1983); *Gully v. First Nat. Bank in Meridian*, 299 U.S. 109, 115 (1936) ("A genuine and present controversy, not merely a possible or conjectural one, must exist with reference thereto. . ."). *Id.* at 113 (citations omitted). In *Shulthis v. McDougal*, 225 U.S. 561 (1911), the Court stated:

A suit to enforce a right which takes its origin in the laws of the United States is not necessarily, or for that reason alone, one arising under those laws, for a suit does not so arise unless it really and substantially involves a dispute or controversy respecting the validity, construction, or effect of such a law, upon the determination of which the result depends.

*Id.* at 569 (emphasis added).

Similarly, under the rule set forth in *Franchise Tax Board*, federal courts have jurisdiction over cases which present state created causes of action only if "a well-pleaded complaint establishes . . . that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law." 463 U.S. at 27-28. Applying the *Franchise Tax Board* test, the court of appeals in the instant case found that Respondents' right to relief on the theory of negligence does not necessarily depend on resolution of an issue of federal law. The court of appeals reasoned that Respondents rely on the FDCA as one available criterion or test which the Ohio court could apply in determining whether Petitioner was negligent and, there-

fore, Petitioner could be found negligent without resolving the federal issue.

This rationale is consistent with this Court's statement in *Gully*:

[A] finding upon evidence that the Mississippi law has been obeyed may compose the controversy altogether, leaving no room for a contention that the federal law has been infringed. The most one can say is that a question of federal law is lurking in the background, . . . .

299 U.S. at 117.

Petitioner misconstrues the nature of Respondents' complaints and, in particular, their fourth causes of action, in asserting that the court of appeals misapplied the *Franchise Tax Board* test by treating Respondents' first and fourth causes of action collectively. Other federal courts considering complaints that allege general negligence in one count, or cause of action, and negligence based on violation of a federal statute in another count, or cause of action, have recognized that the legal basis for the relief sought is the same in both counts, namely, negligence. See *Owens v. New York Central Railroad Co.*, 267 F.Supp. 252 (E.D.Ill. 1967); *Boncek v. Pennsylvania R. Co.*, 105 F.Supp. 700 (D.N.J. 1952).

In *Owens*, plaintiff's complaint consisted of seven counts or causes of action. Counts I, III, V, VI and VII were based on general negligence and breach of warranty. Counts II and IV alleged negligence based on violation of the Safety Appliance Act, particularly 45 U.S.C. § 2. *Id.* at 253. The defendants removed the case to district court on the ground that it arose under the federal law. The plaintiff moved for remand and the district court granted the motion. In reviewing the legal bases of the complaint, the court stated:

Considering the complaint in its entirety and each count separately, the basis upon which the action is founded is negligence or breach of warranty;

and it makes no difference whether the negligence pleaded is founded on common law principles or upon the violation of state or federal statute, still the gist of the action is negligence.

The gravaman [sic] of the cause of action stated in Counts II and IV is negligence and, the cause of action being based on negligence, the alleged violation of the statute is merely one of the props utilized here to support the negligence allegations. *That one of the props is the alleged violation of a federal statute does not remove the cause of action from the realm of negligence. . . .*

*Id.* at 255 (emphasis added).

*Boncek v. Pennsylvania R. Co.* involved numerous actions against multiple defendants for damages resulting from an explosion of munitions. The complaints in certain of the actions contained six counts. The first count alleged general negligence and the fifth count alleged negligence based on violation of the applicable statutes and regulations of the United States, the State of New Jersey and the City of South Amboy, New Jersey. *Id.* at 702. The fifth count specifically identified the regulations of the United States Coast Guard, 46 C.F.R. §§ 142-146, inclusive, and 49 C.F.R. § 73, as well as a New Jersey statute and a city ordinance. *Id.* at 705. The defendants removed the cases and plaintiffs moved to remand. Addressing the issue of federal question jurisdiction, the court stated:

The gravamen of the claims in these suits is that the negligence of the defendants caused the explosion which resulted in damage to the plaintiffs. It is true that one of the charges of negligence embraces a failure to comply with federal statutes and regulations prescribed for the handling, transportation, etc. of explosives. But no recovery is sought under and by virtue of the terms of any federal statutes or regulations. The right of action for the breach of such duty (if we assume that Congress by such statutes and regu-

lations prescribed absolute duties and created correlative rights in favor of injured persons) was created by and enforceable under the laws of the State of New Jersey, and does not really and substantially involve a controversy respecting the validity or construction of a law of the United States upon the determination of which the result depends. . . .

*Id.* at 706 (emphasis added).

The second prong of the *Franchise Tax Board* test encompasses the general rule enumerated in *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1920), which the district court applied in ruling on Respondents' motion to remand. In *Smith*, plaintiff brought a suit in federal court to enjoin a trust company from investing its funds in farm loan bonds issued by federal land banks or joint stock land banks under the authority of the Federal Farm Loan Act of July 17, 1916, as amended. The sole basis for seeking the injunction was that the Federal Acts were unconstitutional and void. In its examination of the jurisdictional issue, this Court stated:

The bill prays that the acts of Congress authorizing the creation of the banks, especially sections 26 and 27 thereof, shall be adjudged and decreed to be unconstitutional, void and of no effect, and that the issuance of the farm loan bonds, and the taxation exemption feature thereof, shall be adjudged and decreed to be invalid.

\* \* \*

The company is authorized to invest its funds in legal securities only. The attack upon the proposed investment in the bonds described is because of the alleged unconstitutionality of the acts of Congress undertaking to organize the banks and authorize the issue of the bonds. *No other reason is set forth in the bill as a ground of*

*objection to the proposed investment by the board of directors acting in the company's behalf. . . .*

\* \* \*

The general rule is that, where it appears from the bill or statement of the plaintiff that the right to relief depends upon the construction or application of the Constitution or laws of the United States, and that such federal claim is not merely colorable, and rests upon a reasonable foundation, the District Court has jurisdiction under this provision.

\* \* \*

The objecting shareholder avers in the bill that the securities were issued under an unconstitutional law, and hence of no validity. *It is therefore apparent that the controversy concerns the constitutional validity of an act of Congress which is directly drawn in question. The decision depends upon the determination of this issue.*

*Id.* at 198-201 (emphasis added).

Smith could not succeed in his suit to enjoin the banks without a declaration that the Federal Act was unconstitutional. He pled no alternative ground on which an injunction could issue. His right to relief, therefore, depended on the construction of federal law. In contrast, Respondents have alleged alternative bases on which Petitioner could be found negligent. Although specific provisions of the FDCA may, or even will, be used as a standard of care for determining negligence, Respondents' right to relief under the theory of negligence *does not depend on application of the provisions.*

Other courts also have reached similar conclusions in assessing the effect of allegations of statutory violations in determining federal question jurisdiction. In *Guthrie v. Alabama By-Products Co.*, 328 F.Supp. 1140 (N.D.Ala.

1971), *aff'd per curiam*, 456 F.2d 1294 (5th Cir. 1972), *cert. den.*, 410 U.S. 946 (1973), *reh. den.*, 411 U.S. 910 (1973) lower riparian landowners sued industrial corporations in federal court for damages and injunctive relief for alleged water pollution. The original complaint alleged federal question jurisdiction on the theory that defendants were depositing refuse in navigable waters in violation of section 13 of the Rivers and Harbors Appropriation Act of 1899, 33 U.S.C. § 407. In addition, the plaintiffs alleged liability for the same acts under common law theories of negligence, trespass and nuisance. The defendants moved to dismiss for lack of subject matter jurisdiction. The plaintiffs, thereupon, filed amendments to the complaint which, *inter alia*, urged pendant jurisdiction of their non-federal claims and divided their claims into six separate counts. One count asserted claims based upon violations of 33 U.S.C. § 407. The other counts alleged negligence, willful and wanton misconduct, nuisance and deprivation of property in violation of 42 U.S.C. § 1983 and the Fifth and Fourteenth Amendments. *Id.* at 1442.

In determining the availability of federal question jurisdiction for the alleged violation of 33 U.S.C. § 407 (Rivers and Harbors Appropriation Act), the court examined the legislative history of the Act and concluded that a private right of action could not be implied under the Act. In addition, the court stated:

First, it is clear that the plaintiffs' right to relief does not depend exclusively upon the existence of 33 U.S.C.A. § 407, or upon whether the defendants are violating that statute. The law of Alabama recognizes a right of action for past damages, as well as a right to injunctive relief to prevent future damages, for impairment of the value and enjoyment of riparian lands resulting from water pollution. . . .

*Id.* at 1144 (emphasis added).

The court, therefore, concluded (1) that the Act did not create a cause of action for individuals damaged as a result of violations of the Act and (2) that the plaintiffs' right to relief did not necessarily depend on whether there was a violation of the Act and held that federal jurisdiction was not available.

In *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983), the plaintiff filed a complaint in state court, alleging two causes of action. The first cause of action sought damages for defendants' failure to comply with tax levies issued under state law. The second cause of action sought a declaration that the defendants were legally obligated to honor all future levies on the ground that the defendants contended that section 514 of the Employment Retirement Income Security Act (ERISA) of 1974, 88 Stat. 829, 29 U.S.C. § 1001, *et seq.*, preempts state law and that the defendants lack the power to honor the levies. The defendants removed the case to federal court, and the plaintiff moved for remand. The district court denied the motion. An appeal was taken ultimately to this Court, which held that the case was improperly removed.

After discussing the various rules articulated in the past for determining the availability of federal question jurisdiction, this Court stated:

Simply to state these principles is not to apply them to the case at hand. Appellant's complaint sets forth two "causes of action," one of which expressly refers to ERISA; if either comes within the original jurisdiction of the federal courts, removal was proper as to the whole case.

*Id.* at 13.

The Court's statement does not dictate that a lower federal court should not consider the basis of a plaintiff's right to relief in each cause of action before determining whether a particular cause of action arises under federal law. In *Franchise Tax Board*, the causes of action sought two types of relief. The first sought coercive relief, whereas

the second sought declaratory relief. As to the second cause of action, the Court stated:

Not only does appellant's request for a declaratory judgment under California law clearly encompass questions governed by ERISA, but appellant's complaint identifies no other questions as a subject of controversy between the parties. Such questions must be raised in a well-pleaded complaint for a declaratory judgment. Therefore, it is clear on the face of its well-pleaded complaint that appellant may not obtain the relief it seeks in its second cause of action . . . without a construction of ERISA and/or an adjudication of its pre-emptive effect and constitutionality—all questions of federal law.

*Id.* at 14 (footnote omitted). Although the questions governed by ERISA appeared on the face of the plaintiff's fourth cause of action and the relief sought required a construction of ERISA, the Court found that the cause of action did not arise under federal law. The Court looked beyond the request for declaratory relief to the underlying coercive action that might be brought absent the availability of declaratory relief, and determined that the plaintiff's right to coercive relief did not depend on a construction of ERISA.

In the instant case, the court of appeals analyzed Respondents' fourth cause of action "with an eye to practicality and necessity." *Id.* at 20. It recognized that the common predicate or basis of Respondents' first and fourth causes of action was the state law theory of negligence, and determined that Respondents' right to relief under that theory did not depend on resolving the federal issue. The court of appeals' collective treatment of Respondents' first and fourth causes of action is consistent with this Court's statement in *Baltimore S.S. Co. v. Phillips*, 274 U.S. 316, 321 (1926):

A cause of action does not consist of facts, but of the unlawful violation of a *right* which the

facts show. The number and variety of the facts alleged do not establish more than one cause of action so long as their result, whether they be considered severally or in combination, is the violation of but one right by a single legal wrong. *The mere multiplication of grounds of negligence alleged as causing the same injury does not result in multiplying the causes of action.* "The facts are merely the means, and not the end. They do not constitute the cause of action, but they show its existence by making the wrong appear."

*Id.* at 321 (citation omitted) (emphasis added).

Petitioner's reliance on *United Mine Workers v. Gibbs*, 383 U.S. 715 (1966), in attempting to establish what the Franchise Tax Board Court meant by cause of action, is misplaced. In effect, Petitioner puts the cart before the horse in its analysis, by initially presupposing that Respondents' first and fourth causes of action state separate claims, one state and one *federal*. However, *both* the first and fourth causes of action in Respondents' complaints are state-created, as Petitioner clearly admits. Petitioner's Brief at p. 10.

In *Gibbs*, plaintiff brought suit in federal court for damages, alleging that he lost his job and trucking contracts as a result of the activities of the defendant in a violent labor dispute. His complaint alleged violations of section 303 of the Labor Management Relations Act, 1947, 61 Stat. 158, as amended, and the common law of Tennessee. Jurisdiction was premised on allegations of secondary boycotts under section 303, which provides for a private right of action for any individual injured in his property or business as a result of secondary boycotts. The complaint in *Gibbs* sought relief directly under section 303. If the facts alleged in the complaint had constituted secondary boycotts, Gibbs would have had a right to relief under section 303. Thus, Gibbs' claim of secondary boycotts under section 303 was a *federal* claim. Because it was a federal claim vesting subject matter jurisdiction in the district

court, the district court had pendant jurisdiction to hear Gibbs' state claim.

Only *after* one of several causes of action is determined to create federal question jurisdiction does the power of pendant jurisdiction vest. If a claim is state-created, the second prong of the *Franchise Tax Board* test must be applied *before* making a determination that federal question jurisdiction exists. The holding in *Gibbs* does not foreclose analysis of a state-created "cause of action" in terms of the legal theory on which it is predicated before applying the *Franchise Tax Board* test. As previously noted, the Court in *Franchise Tax Board* analyzed the plaintiff's second cause of action for declaratory relief "with an eye to practicality and necessity," before applying its own test.

As the court of appeals noted at the outset of its inquiry, the propriety of removal turns upon whether federal question jurisdiction would exist if the actions were originally brought in federal court. J.A. 9. In light of Congress' express refusal to provide a private right of action under the FDCA because it would duplicate available state remedies,<sup>3</sup> it would appear illogical that a federal court would have original jurisdiction over Respondents' allegations of violation of the FDCA merely because they were alleged under a separate "cause of action" as an alternative ground for relief under the common law theory of negligence.

**B. A Claim That Alleges A Common Law Theory Of Negligence Based On The Violation Of A Duty Imposed By A Federal Penal Statute Does Not Constitute An Independent Basis For Federal Jurisdiction.**

The courts of various states have created, on common law principles, or by statute, liability for breach of a state or federal penal statute, when the breach results in injury of the kind the statute was intended to prevent. If the claim invokes the provisions of a federal safety statute pursuant to the state-created theory of liability, a reference to a federal statute necessarily will appear on the

<sup>3</sup>See fn. 2, *supra*.

face of the complaint. Nonetheless, this Court and lower federal courts have consistently stated that such claims do not vest subject matter jurisdiction in a federal court when diversity of citizenship is absent.

This Court specifically addressed the issue of whether state-created claims based on violation of a federal safety statute give rise to federal question jurisdiction in *Moore v. Chesapeake & O. Ry. Co.*, 291 U.S. 205 (1934). The *Moore* case was brought in federal court by an employee of the defendant alleging injuries sustained in the defendant's railroad yard in Kentucky. The first count alleged injuries incurred in interstate commerce and was brought under the Federal Employers' Liability Act and Federal Safety Appliance Acts. The second count alleged that the injuries were received in intrastate commerce and cited the Federal Safety Appliance Acts for claims brought under the Employers' Liability Act of Kentucky.

In the second count, *Moore* alleged diversity of citizenship. At the time he filed suit, the venue statutes provided that a suit founded solely on diversity of citizenship could be brought in either the plaintiff's or defendant's place of residence, whereas a suit founded, solely or in part, on the existence of federal question jurisdiction could be brought only in the defendant's place of residence. Based on these venue restrictions, the defendant objected to the jurisdiction of the district court as to each count. The district court rejected defendant's objections and entered judgment for the plaintiff. On appeal, the court of appeals reversed, holding that the district court did not have jurisdiction to hear either count. The court of appeals, in reaching its opinion, reasoned that the second count attempted to set forth a claim under the Safety Appliance Acts and concluded that jurisdiction was not based solely on diversity of citizenship.

On review, the threshold issue faced by this Court was to determine whether plaintiff's counts presented a federal issue sufficient to confer federal question jurisdiction. The Court reasoned that under the Federal Employers' Lia-

bility Act, an employee has a private right of action for violation of the Safety Appliance Acts and held that the first count set forth a federal cause of action. As to the second count, the Court stated:

While invoking, in the second count, the Safety Appliance Acts, petitioner fully set forth and relied upon the laws of the state of Kentucky where the cause of action arose. . . . The Kentucky act provided that no employee should be held "to have assumed the risk of his employment" in any case "where the violation by such common carrier of any statute, State or Federal, enacted for the safety of employees contributed to the injury or death of such employee."

\* \* \*

Questions arising in actions in state courts to recover for injuries sustained by employees in intrastate commerce and relating to the scope or construction of the Federal Safety Appliance Acts are, of course, federal questions which may appropriately be reviewed in this Court. . . . *But it does not follow that a suit brought under the state statute which defines liability to employees who are injured while engaged in intrastate commerce, and brings within the purview of the statute a breach of the duty imposed by the federal statute, should be regarded as a suit arising under the laws of the United States and cognizable in the federal court in the absence of diversity of citizenship.* The Federal Safety Appliance Acts, while prescribing absolute duties, and thus creating correlative rights in favor of injured employees, did not attempt to lay down rules governing actions for enforcing these rights.

\* \* \*

The Safety Appliance Acts having prescribed the duty in this fashion, the right to recover damages

sustained by the injured employee through the breach of duty sprang from the principle of the common law . . . and was left to be enforced accordingly . . . .

*Id.* at 212-215 (citations omitted) (emphasis added).

While in *Moore* the ultimate issue concerned venue, to reach that issue, it was necessary for the Court to determine whether a state law claim invoking a federal safety act was cognizable in federal court in the absence of diversity of citizenship. The Court recognized that such claims present an issue of federal law but did not deem the federal issue sufficient to warrant primary adjudication in the federal courts. As the Court's discussion indicates, the availability of review by this Court on *certiorari* is sufficient to protect the federal interest involved. The underlying premise of the Court's analysis was that the effect of the federal statute in the resolution of the state claim is determined by state law. Therefore, the interests of the state in adjudicating the claim overshadows the federal interest involved.

This premise was applied and fully explained in *Jacobson v. New York, N.H. & H.R. Co.*, 206 F.2d 153, *aff'd per curiam*, 347 U.S. 909 (1954). The action was filed in federal district court alleging wrongful death resulting from injuries incurred while the decedent was a passenger on the defendant's train. The amended complaint alleged jurisdiction based on the existence of a question under the Safety Appliance Acts, 45 U.S.C. §1, *et seq.* In support of federal question jurisdiction, it was alleged that decedent's death was caused by defendant's negligent maintenance and operation of the brakes and couplings in violation of the provisions of the federal statute. On review of the district court's dismissal for lack of subject matter jurisdiction, the First Circuit held that the cause of action invoking the Safety Appliance Acts was not within the jurisdiction of the court under 28 U.S.C. § 1331.

The First Circuit noted that although Congress did not create a statutory right of action in favor of passengers

injured as a result of violations of the Safety Appliance Acts, the courts may create a right of action on the principles of the common law by regarding the breach of a penal statute as an operative fact on which common law tort liability may be predicated. The court then discussed the various common law principles developed by the states:

The courts of the various states differ extensively in their formulation and application of the common law principle upon which a liability is created in favor of a person injured by breach of a criminal statute. Some courts speak of the breach as "negligence *per se*", others as "evidence of negligence" or as "prima facie evidence of negligence." Nor are they completely in agreement as to what is meant by these phrases. Furthermore, liability in such cases is fitted into whatever local variations there may be in common law doctrines as to contributory negligence, last clear chance, assumption of risk, proximate cause, etc.

*Id.* at 156. The court further stated:

If the federal courts had undertaken to apply this [common law] principle as a matter of federal decisional law, in the case of a breach of the Safety Appliance Acts resulting in personal injury to a person not entitled to sue under the Employers' Liability Acts, and if such liability had been imposed as a matter of federal common law without reference to local variation of statutory law or of common law doctrine applicable in the state where the injury occurred, it would perhaps follow that a complaint setting up such a liability would be a civil action arising "under the Constitution, laws or treaties of the United States" within the meaning of 28 U.S.C. § 1331.

*Id.* at 157. The court noted that it is "abundantly clear that the courts have not, as a matter of federal common law, developed a private right of action for damages" for

passengers injured as a result of violations of the Safety Appliance Acts. The court concluded that if a passenger brought an action in state court for injuries resulting from a breach of the Acts, "issues bearing upon the right to recovery, relating, for example, to common law doctrines of last clear chance, the defense of contributory negligence, or proximate cause, depend upon the local law of the state." *Id.* at 157.

The holdings in *Moore* and *Jacobson* are not, as Petitioner asserts, based exclusively on the Holmes premise that "a suit arises under the law that creates the cause of action." *American Well Works Co. v. Layne & Bowler Co.*, 241 U.S. 257, 260 (1916). As the *Jacobson* opinion reveals, the rationale underlying these holdings is not susceptible to such categorical reduction. The First Circuit's examination of the state issues involved in a state law negligence claim based on violation of a federal penal statute demonstrates that the state issues inherent in such a claim predominate over the apparent federal issue. Stated in terms of policy, the interest of the state in resolving such claims outweighs the federal interest.

In *Crane v. Cedar Rapids & Iowa City Railway Co.*, 395 U.S. 164 (1969), the Court discussed the relationship between state law theories of negligence and violation of a federal safety statute. The case, which was brought in state court, was reviewed by this Court on *certiorari* to the state supreme court. The issue before the Court was whether a state may make the defense of contributory negligence available to a railroad sued by a nonemployee for injuries caused by the railroad's failure to maintain its freight cars in accordance with the provisions of the Safety Appliance Acts, 45 U.S.C. § 2. The Court determined that the present federal statutory scheme does not create a federal cause of action for nonemployees injured as a result of violations of the Safety Appliance Acts. The Court thereafter stated:

[T]he nonemployee must look for his remedy to a common-law action in tort, which is to say that

he must sue in a state court, in the absence of diversity, to implement a state cause of action. . . . "[T]he right to recover damages sustained . . . through the breach of duty sprang from the principle of the common law . . . and was left to be enforced accordingly. . . ." In consequence, *we have consistently held that under the present statutory scheme the definition of causation and the availability of the defenses of assumption of risk and contributory negligence are left to state law.*

*Id.* at 166-167 (emphasis added) (citations omitted).

*Crane* did not involve the issue of federal jurisdiction. However, the holding is relevant to the issues before this Court. In *Crane*, the Court recognized that the states have a significant interest in litigating claims alleging negligence based on violation of a federal safety statute. When no federal right of action exists, issues bearing on the plaintiff's right to recover on such claims are important state concerns which should be left to be enforced by the states.

Lower federal courts have overwhelmingly held that negligence claims based on violations of federal safety statutes should be heard in state court. In *Andersen v. Bingham & G. Ry. Co.*, 169 F.2d 328 (10th Cir. 1948), the district court remanded a case alleging a violation of the Safety Appliance Acts, 45 U.S.C. § 1, *et seq.*, as one of ten separate grounds of negligence. The court stated that the allegation merely tendered an issue of fact as to whether the requirements of the Acts were violated. *Id.* at 330. In *Dennis v. Southeastern Aviation, Inc.*, 176 F.Supp. 542 (1959), the plaintiff alleged violations of the rules and regulations of the Federal Civil Aeronautics Act. The district court remanded the case on the ground that the allegation simply tendered another issue of negligence. *Id.* at 254.

Lower courts considering allegations of violation of the FDCA in actions brought by private individuals have held

that the allegations do not create federal question jurisdiction and, therefore, must be heard in state court. In *Gelley v. Astra Pharmaceutical Products, Inc.*, 466 F.Supp. 182 (D.Minn. 1979), *aff'd*, 610 F.2d 558 (8th Cir. 1979), the court dismissed the plaintiff's action for lack of subject matter jurisdiction, stating:

This court . . . holds that the Food, Drug and Cosmetic Act does not, by implication, provide a monetary remedy to a private person injured as a result of a violation of the Act. *Cort v. Ash*, 422 U.S. 66, 75 S.Ct. 2080 (1975).

As there exists no private cause of action for a violation of the Act, there is no federal question jurisdiction. . . . As the parties are not diverse, it necessarily follows that this Action must be dismissed for lack of subject matter jurisdiction.

*Id.* at 187, *aff'd*, 610 F.2d 558 (citations omitted).

In *State of Florida ex rel. Broward County v. Eli Lilly & Co.*, 329 F.Supp. 364 (S.D.Fla. 1971), the state sued in federal district court on its own behalf, and on behalf of consumers who sought monetary damages under the FDCA. In dismissing the action on the ground that violations of the FDCA do not constitute an independent basis for federal question jurisdiction, the court stated:

There is no need to decide whether under Florida law violation of the [Federal Food, Drug and Cosmetic] Act constitutes negligence *per se*, for absent diversity, a complaint that alleges common law theories of recovery based upon the violation of a duty owed under a federal statute must be brought in State court.

*Id.* at 366 n. 3 (citations omitted).

As will be discussed in Point II of Respondents' Brief, Respondents' allegation that Petitioner misbranded Bendectin in violation of the FDCA does not present a novel federal question requiring the unique abilities of a federal

court. Therefore, their allegation is not distinguishable from the allegations considered in *Moore*, *Jacobson* or other decisions cited above.

**C. Allegations That Petitioner Violated Provisions Of The Food, Drug And Cosmetic Act Constitute A Response Made In Anticipation Of Defenses Petitioner May Assert And, Therefore, Do Not Give Rise To Federal Question Jurisdiction.**

The well-pleaded complaint rule provides a substantive test for determining whether Respondents' fourth causes of action "arise under" federal law within the meaning of 28 U.S.C. § 1331. The rule was set forth in *Taylor v. Anderson*, 234 U.S. 74 (1914), as follows:

[W]hether a case is one arising under the Constitution or a law or treaty of the United States in the sense of the jurisdictional statute . . . must be determined from what necessarily appears in the plaintiff's statement of his own claim, *unaided by anything alleged in anticipation of avoidance of defenses which it thought the defendant may interpose.*

*Id.* at 75-76 (emphasis added). The rule was recently expressed by the Court in *Franchise Tax Board*: "A federal court does not have original jurisdiction over a case in which the complaint presents a *state-law cause of action*, but also asserts that *federal law deprives the defendant of a defense he may raise.*" 363 U.S. at 10 (emphasis added).

Allegations of violations of federal safety statutes in support of state law negligence claims, if established, will, on state common law principles, or by statutes, limit the defenses available to the defendant. The extent to which such allegations will burden the defense will depend on the law of the particular state.

The legal effect of violations of the FDCA in the instant case will be determined by the common law of Ohio. In Respondents' complaints, they allege that the violation of the federal statute constitutes "a rebuttable presumption

of negligence." J.A. 32. In Respondents' motion to remand, they point out that violation of a state or federal safety statute constitutes "negligence *per se* under Ohio law."<sup>4</sup> However, no matter how a violation of the federal statute functions in establishing negligence under Ohio law, a violation will *deprive the defendant of some defense he may raise.*

If violation of the federal safety statute is negligence *per se* under Ohio law, then a finding that the statute was violated will deprive Petitioner of any defenses to a claim of negligence available under Ohio law. If violation of the statute constitutes a rebuttable presumption of negligence, then a finding of a violation will shift the burden of proof to Petitioner, thereby foreclosing the defense that negligence was not shown by a preponderance of the evidence. If violation of the statute is considered only evidence of negligence, then a finding that the statute was violated will deprive Petitioner of the defense that it acted in conformity with the customs of the pharmaceutical industry and, hence, acted reasonably. Thus, at the very least, the allegation of violation of the statute is a response anticipating that Petitioner will assert that it met the standard of care of a reasonable drug manufacturer.

For the foregoing reasons, Respondents' fourth causes of action are state law causes of action in negligence which assert that federal law deprives the defendant of a defense he may raise and, therefore, do not vest original jurisdiction in the federal court.

<sup>4</sup>Under Ohio law, violation of a specific safety statute is negligence *per se*, rendering the defendant liable if his negligence caused or contributed to causing the plaintiff's injury. *Shroades v. Rental Homes, Inc.*, 68 Ohio St. 2d 20, 427 N.E.2d 774 (1981); *Freeman v. United States*, 509 F.2d 626, 630 (6th Cir. 1975).

**II. WHERE A PRIVATE LITIGANT SEEKS A MONETARY REMEDY ON THE THEORY OF NEGLIGENCE AND ALLEGES, *INTER ALIA*, THAT A DRUG MANUFACTURER VIOLATED PROVISIONS OF THE FDCA, THE ALLEGATIONS DO NOT CREATE A FEDERAL INTEREST SUFFICIENT TO REQUIRE RESOLUTION BY A FEDERAL COURT.**

**A. State Applications Of Provisions Of The FDCA In Suits Involving Only Private Litigants Will Not Affect The Federal Scheme Regulating Pharmaceuticals.**

Section 307 of the Food, Drug and Cosmetic Act, 21 U.S.C. § 337, provides that "all" proceedings for the enforcement of the Act or to restrain violations of the Act "shall be by and in the name of the United States." Moreover, federal courts considering claims by private litigants for money damages or injunctive relief have uniformly refused to imply a private right of action under the Act on the ground that Congress expressly declined to provide one. See *National Women's Health Network, Inc. v. A.H. Robins, Inc.*, 545 F.Supp. 1177, 1179 (D.Mass. 1982)<sup>5</sup> Therefore, a body of federal common law has not been developed to govern such claims.

Since Congress has established that the provisions of the FDCA are only to be enforced publicly, resolution of claims involving only private litigants by a federal court will not promote a significant federal interest. Moreover, resolution of the claims by the Ohio court will not burden the United States in the enforcement of the FDCA or frustrate the operations of the Food and Drug Administration.

In *Howard v. Group Hospital Service*, 739 F.2d 1508 (10th Cir. 1984), the court concluded that if state court resolution of a claim will not adversely affect a federal interest, federal question jurisdiction should not be in-

<sup>5</sup>See *Hearings on S. 1944* (Subcommittee of Committee on Commerce), 73d Cong., 2d Sess.

voked. The *Howard* case was brought in state court for damages in tort and contract resulting from Blue Cross' failure to pay claims under a Federal Employee Health Benefit Program (FEP) on the basis that there was no medical necessity for the treatment. Blue Cross removed the case and the district court denied remand. Under 5 U.S.C. § 8901-13, the Office of Personnel Management (OPM) contracts for and approves health benefit plans covering federal employees, and the federal government subsidizes the subscription charge. Blue Cross, which had a contract with the OPM setting forth an approved plan, argued that federal law should apply to the interpretation of the contract. On review, the court of appeals stated:

[W]hen the federal government has an articulable interest in the outcome of a dispute, federal law governs. Thus, if diverse resolutions of a controversy would frustrate the operations of a federal program, conflict with a specific national policy, or have some direct effect on the United States or its treasury, then federal law applies. . . . We fail to see how various state court adjudications of FEP benefits claims will frustrate the operation of that program or conflict with a specific national policy.

*Id.* at 1510-1511 (citations omitted) (footnote omitted). On that premise, the court remanded the case, holding that the claim "is a private controversy in which the federal government simply does not have an interest sufficient to justify invoking federal question jurisdiction." *Id.* at 1512.

In determining the presence of federal question jurisdiction, the court in *Howard* relied heavily on *Miree v. DeKalb County*, 433 U.S. 25 (1977), in which petitioners brought actions, arising out of an air crash, in federal court. Their complaints alleged that they were third-party beneficiaries of grant contracts between the county and the Federal Aviation Administration, and that the county breached the contracts by maintaining a garbage dump adjacent to the airport that attracted birds and caused

them to be drawn into the jet engines. Although the claims were brought on the basis of diversity of citizenship, the court of appeals held that the application of federal law was required because the United States was a party to the contract. The Supreme Court reversed, based on the following rationale:

*While federal common law may govern even in diversity cases where a uniform national rule is necessary to further the interests of the federal government . . . , the application of federal common law to resolve the issue presented here would promote no federal interest. . . . [T]he resolution of petitioners' breach-of-contract claim against the respondent will have no direct effect upon the United States. . . . Since only the rights of private litigants are at issue here we find the Clearfield Trust rationale inapplicable.*

*Id.* at 29 (footnotes omitted) (emphasis added). The Court further stated:

*In deciding whether rules of federal common law should be fashioned, normally the guiding principle is that a significant conflict between some federal policy or interest and the use of state law in the premises must first be specifically shown. . . . Whether latent federal power should be exercised to displace state law is primarily a decision for Congress.*

*Id.* at 31-32, quoting *Wallis v. Pan American Petroleum Corp.*, 384 U.S. 63, 68 (1966) (emphasis added).

When state law brings a federal safety statute within its scope, the state law, in effect, points to the federal statute as establishing a standard of care. Thus, in the subject actions, the provisions of the Federal Food, Drug and Cosmetic Act function as a criterion for determining whether Petitioner has satisfied the duty of care prescribed by Ohio's common law theory of negligence. State law application of specific provisions of the Federal Food, Drug and Cosmetic Act in disputes involving only private liti-

gants will not frustrate the operations of the Federal Food and Drug Administration. As will be shown in the following two sections, the allegations in Respondents' fourth causes of action rely on well-defined and straightforward provisions that can be applied by the Ohio court. Moreover, Respondents' foreign citizenship and extraterritorial ingestion of Bendectin (Debendox) are simply factual issues regarding whether Petitioner developed, tested, promoted, manufactured, or sold the drug products in Ohio or directed any of these activities from Ohio, as to which the parties do not agree. This disputed factual issue, moreover, does not bear on any question relating to the scope or construction of the FDCA.

**1. State courts routinely apply provisions of safety statutes like the Federal Food, Drug and Cosmetic Act under their power to decide the common law of their jurisdiction.**

State courts routinely are asked to decide whether a violation of a federal statute will be used to establish a standard of care from which it is negligence to deviate. In other words, in their function as exponents of the common law, courts in each jurisdiction continually must decide whether, and to what effect, a violation of a federal statute will be used to establish a standard of care for their jurisdiction. In reaching these decisions, however, the state court does not seek to set forth pronouncements on the function or effect of the statute in the federal regulatory system; rather, the court seeks only to determine whether the Act *should be applied to afford protection* against the conduct of the defendant. This Court, moreover, has long recognized that state courts can and are willing to properly apply federal law. *Commonwealth of Pennsylvania v. Nelson*, 377 Pa. 58, 104 A.2d 133 (1954), *aff'd*, 350 U.S. 881 (1955).

Indeed, there are few provisions of federal law as devoid of ambiguity and as fully explained as the misbranding regulations for the FDCA. See 21 C.F.R. § 201.1. For example, 21 C.F.R. § 201.57(g) sets forth in explicit detail what a drug manufacturer must disclose in its labeling to

avoid having its drug found to be misbranded (false and misleading). Similarly, 21 C.F.R. § 202.1(e)(6) describes in detail the type of advertisement that would be false and misleading and violative of section 502(n) of the FDCA. In fact, the regulatory scheme enunciated by these regulations is, in most instances, far clearer than the typical jury instructions on the issue of negligence we commonly ask jurors to apply to the facts of the negligence.<sup>6</sup> In effect, all the court must do is to command the jury to determine whether the particular regulations at issue have been violated and, if so, whether the plaintiff's injuries are of the type which the regulation intended to avoid. Of course, the court may, under this definition of negligence *per se*, direct a verdict for the plaintiff, but courts always have this power to direct verdicts when the evidence dictates that they do so. Directing a verdict, however, is not tantamount to engaging in legislative interpretation.

In this respect, the Court is asked to take judicial notice of the provisions of Ohio law, OHIO REV. CODE ANN. § 3715.01, *et seq.*, which are identical to the federal misbranding statutes under 21 U.S.C. § 352. *Newcomb v. Brennan*, 558 F.2d 825 (8th Cir. 1977), *cert. den.*, 434 U.S. 968 (1977). In the instant case, the state court, in attempting to decide the applicability of the FDCA misbranding provisions, will be forced to factor into its calculus

<sup>6</sup>Compare Civil Jury Instruction 5-1, "Negligence Defined," *Standardized Civil Jury Instructions for the District of Columbia*, Revised Edition ("Negligence is the failure to exercise ordinary care. This negligence is doing something a person using ordinary care would not do, or not doing something a person using ordinary care would do. Ordinary care means that caution, attention or skill a reasonable person would use under similar circumstances"), with 21 C.F.R. § 202.1(e)(6)(iv) ("An advertisement is false . . . or otherwise misleading . . . (iv) Contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated.")

the Ohio State Legislature's intention in passing legislation identical to that found in the FDCA. In other words, the focus is not on the implementation of the FDCA, but rather on whether the common law of the State of Ohio will adopt as a standard of care in a tort action provisions making the misbranding of drugs evidence of negligence *per se*.

#### **B. Respondents Seek Damages For Negligent Acts By The Petitioner That Occurred In The State Of Ohio.**

Petitioner's suggestion that Respondents seek extraterritorial application of the FDCA is without merit. Petitioner, in its argument, claims that the Bendectin ingested by the Respondents was manufactured overseas and consumed overseas and, therefore, reasons that any violations of American law in the development, testing, and marketing of Bendectin that occurred in Ohio cannot form the basis of liability for the overseas Respondents.

This approach fails to consider significant events that clearly demonstrate that operative facts of negligence surrounding the manufacture and distribution of Bendectin occurred in Ohio. Bendectin, in all of its formulations, was developed and tested in Ohio. Moreover, the marketing of Bendectin was directed from Ohio, as was its labeling and advertising. Animal and human testing also was done primarily in Ohio. Manufacture of at least some of the drug sold abroad also was performed in Ohio. Similarly, the sale of Bendectin throughout the world was directed from Ohio.

If Petitioner violated the FDCA in the development, testing or sale of Bendectin, Ohio has a paramount interest in regulating Petitioner's conduct. *Lake v. Richardson-Merrell*, 538 F.Supp. 262 (N.D. Ohio 1982). Petitioner's assertion that only a federal court can properly determine the appropriate standard of care required of a drug manufacturer in Ohio, therefore, is without merit.

#### **C. The Federal Interest In Resolving Respondents' Claims, Or Similar Claims, If Any, Is Not Sufficient To Warrant A Finding That Will Open The Federal Courts To Countless Claims Now Resolved by State Courts.**

Congress has created federal statutes regulating the activities of many industries that affect the national welfare.

If the Court holds that state law negligence claims alleging violations of the statutes create federal question jurisdiction, then every plaintiff suing a party subject to federal regulation upon the theory of negligence will have access to the federal courts. An artful pleader will be able to invoke federal jurisdiction merely by alleging a violation of a federal regulatory provision.

Moreover, it is arguable that cases brought in state court will be removable to federal court if the plaintiff fails to explicitly refer to an appropriate standard that has a federal source. This becomes more probable if the state has not enacted a similar statute of its own. In other words, if a plaintiff bases a negligence claim on allegations that identify specific safety precautions required under a particular federal statute without alleging violation of the statute, the claim would be removable on the ground that it was artfully pleaded to avoid federal jurisdiction.

The Court confronted a similar dilemma relating to state declaratory judgments in *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983). In the *Franchise Tax Board* case, the Court considered the issue of whether the doctrine of *Skelly Oil v. Phillips Petroleum Co.*, 339 U.S. 667 (1950), limits federal jurisdiction under §§ 1331 and 1441 when a question of federal law appears on the face of a well-pleaded complaint for a state-law declaratory judgment. In deciding the issue, the Court stated:

If federal district courts could take jurisdiction, either originally or by removal, of state declaratory judgment claims raising questions of federal law, without regard to the doctrine of *Skelly Oil*, the federal Declaratory Judgment Act—with the limitations of *Skelly Oil* read into it—would become a dead letter. For any case in which a state declaratory judgment action was available, litigants could get into federal court for a declaratory judgment despite our interpretation of § 2201, simply by pleading an adequate state claim for a declaration of federal law.

*Id.* at 18. In holding that federal courts do not have jurisdiction when a federal question is presented by a complaint for a state declaratory judgment, the Court noted:

It is not beyond the power of Congress to confer a right to a declaratory judgment in a case or controversy arising under federal law—within the meaning of the Constitution or of § 1333—without regard to *Skelly Oil*'s particular application of the well-pleaded complaint rule. . . . At this point, any adjustment in the system that has evolved under the *Skelly Oil* rule must come from Congress.

*Id.* at 18 n. 17.

Congress has not created a private right of action under many of its regulatory statutes. When drafting the FDCA, however, Congress expressly determined that a judicial right of action under the Act was unnecessary because the states provide a private remedy. Various state courts, on the other hand, have chosen to apply federal safety statutes on common law principles and decide how they will function in establishing negligence in the particular jurisdiction. Moreover, this Court has held that state courts have the power to make these decisions. *Crane v. Cedar Rapids & Iowa City Railway Co.*, 395 U.S. 164, 167 (1969). To restrict the power of the state to hear state-created negligence claims because they involve a federal statute which grants no private remedies, will greatly increase the dockets of the federal courts without promoting a significant federal interest.

### CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be upheld without modification and the judgment of the district court reversed by this Court.

Respectfully submitted,

STANLEY M. CHESLEY  
WAITE, SCHNEIDER, BAYLESS,  
& CHESLEY

1513 Central Trust Tower  
Fourth and Vine Streets  
Cincinnati, Ohio 45202  
(513) 621-0267

*Counsel for Respondents*

*Of Counsel:*

ALLEN T. EATON

ALLEN T. EATON & ASSOCIATES  
1029 Vermont Avenue, N.W.  
Washington, D.C. 20005

FELICIA C. SMITH  
Law Offices of GEORGE A. KOKUS  
1521 N.W. 15th Street Road  
Miami, Florida 33125

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IN THE  
**SUPREME COURT OF THE UNITED STATES**

OCTOBER TERM, 1985

MERRELL DOW PHARMACEUTICALS INC.,  
Petitioner,  
vs.

LARRY JAMES CHRISTOPHER THOMPSON AND  
DONNA LYNN THOMPSON AS NEXT FRIENDS AND  
GUARDIANS OF JESSICA ELIZABETH THOMPSON,  
LARRY JAMES CHRISTOPHER THOMPSON,  
INDIVIDUALLY AND DONNA LYNN THOMPSON,  
INDIVIDUALLY, *et al.*,  
Respondents.

On Writ of Certiorari to the  
United States Court of Appeals for the  
Sixth Circuit

**REPLY BRIEF FOR PETITIONER**

Frank C. Woodside III  
2100 Fountain Square Plaza  
511 Walnut Street  
Cincinnati, Ohio 45202  
(513) 977-8200  
Counsel for Petitioner

Of Counsel:

John E. Schlosser  
Christine L. McBroom  
DINSMORE & SHOHL  
2100 Fountain Square Plaza  
511 Walnut Street  
Cincinnati, Ohio 45202

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**REPLY BRIEF FOR PETITIONER****REVIEW OF PETITIONER'S CONTENTIONS**

To reply to Respondents' arguments, it is first necessary to clarify what rulings the Petitioner seeks from this Court and what rulings it does not seek. Petitioner's analysis poses two questions. First, does the Respondents' allegation that Petitioner violated the Food, Drug and Cosmetic Act by "misbranding" drugs through misleading promotion of those

drugs render the Fourth Cause of Action one "necessarily dependent" for its resolution on decision of a substantial issue of federal law? Second, if the first question be answered in the affirmative, does the fact that the Respondents also pled other purely non-federal grounds for recovery for the same injuries deprive the district court of jurisdiction over the "federal question" claims asserted in their Fourth Causes of Action?

Petitioner urges that a claim which necessarily depends on a finding that the defendant violated federal law confers federal question jurisdiction under 28 U.S.C. § 1331, if the claim is such that interpretation and construction of federal law will be necessary to the decision of that claim.<sup>1</sup> Petitioner also urges that if a claim is, in this fashion, necessarily dependent on a federal legal interpretation, it is of no significance that a plaintiff has pled parallel claims for the same injuries which do not depend upon federal law for their decision.

Contrary to the Respondents' implication, Petitioner does not urge that federal jurisdiction is present in *any* situation in which a plaintiff brings a non-federally created claim which invokes federal law or which might rely upon federal law. Petitioner's jurisdictional contention is limited, rather, to a situation in which interpretation and construction of federal

<sup>1</sup> Respondents cannot deny that their Fourth Causes of Action allege injuries proximately resulting from the federal violations which they allege. Both courts below accepted without inquiry Respondents' post-removal "concession" that they had no right to a private claim under the Food, Drug and Cosmetic Act. Though they deny any attempt to state a private cause of action under the Food, Drug and Cosmetic Act, Respondents included all elements of such a claim in their pleadings. A reading of the complaints suggests that their mention of a "rebuttable presumption of negligence" was not the gist of their Fourth Causes of Action at all, but merely a gratuitous cross-reference to their First Causes of Action. Had the Respondents been desirous of "federal question" jurisdiction, they need only have added to their complaints an invocation of 28 U.S.C. § 1331. Petitioner's arguments on this independent ground for federal jurisdiction are set forth at pages 36 and 37 of its principal brief and will not be repeated here.

law will obviously be necessary to the determination of the plaintiff's claim. The Petitioner does not impugn the competence of the state courts in *applying* federal law but asks this Court to recognize that concurrent original federal jurisdiction is present where a case requires the *development* of federal law through the construction and interpretation of federal statutes. Where, as here, an interpretation that the statute applies to foreign claims will be prerequisite to a decision to apply it, the application of the statute and its "construction" are synonymous.

## ARGUMENT

### I. RESPONDENTS' SUCCESSFUL PROSECUTION OF THEIR FOURTH CAUSES OF ACTION WILL REQUIRE ADOPTION OF A NOVEL AND EXPANDED VIEW OF THE TERRITORIAL APPLICATION OF THE FOOD, DRUG AND COSMETIC ACT.

Respondents avoid comment on the history of the mass tort litigation involving the American drug Bendectin, its Canadian counterpart of the same name, and the similar British drug "Debendox." Yet, this history explains the novelty of the Respondents' contentions and the reasons why these claims were pled as they were. As Respondents do not dispute, their counsel appeared on behalf of other Canadian and British plaintiffs who previously brought actions in the Southern District of Ohio against the Petitioner. These earlier plaintiffs also attributed their children's birth defects to Debendox and Canadian Bendectin. Their cases were dismissed by the district court on grounds of *forum non conveniens*. Chief among the reasons for these dismissals were that the plaintiffs and their injuries were of foreign origin and that foreign law would likely control the outcome. *In re Richardson-Merrell, Inc.*, 545 F. Supp. 1130 (S.D. Ohio 1982), *aff'd sub. nom. Dowling v. Richardson-Merrell, Inc.*, 727 F.2d 608 (6th Cir. 1984); *Vandervliet v. Richardson-Merrell, Inc.*, Case No.

C-1-82-470, Order Granting Defendant's Motion to Dismiss on *Forum Non Conveniens* Grounds and Judgment of Dismissal (S.D. Ohio Apr. 13, 1984).

The advantages of an American forum to Respondents are discussed at length in the memoranda filed by the parties below concerning the *forum non conveniens* issue. These memoranda are part of the record of this case. Original federal jurisdiction was available to the Respondents by reason of diversity of citizenship,<sup>2</sup> but they wished to avoid the dismissal on grounds of *forum non conveniens* which would certainly ensue if they filed in federal court. Accordingly, they filed their suits in state court, but took the additional step of implying that the drug which they accused of causing their injuries was American Bendectin, rather than Debendox or Canadian Bendectin. This operated to obscure the name and origin of the drugs which were actually available to the Respondent mothers and which they allegedly took. In their complaints, Respondents treated the name "Bendectin" as a generic name and were, thus, able to identify the drug which Mrs. MacTavish actually claims to have taken as "Bendectin," even though the name the British drug actually bore was "Debendox."

The name "Bendectin" is not, however, a generic name but a *brand name*, belonging to *two* products, each licensed and regulated by a different sovereign. One "Bendectin" is the American drug, made and sold in the United States under the

<sup>2</sup> Because of the Respondents' alien citizenship and the amount in controversy, these cases were within the original jurisdiction of the district court under 28 U.S.C. § 1332(a)(2). However, this was not a proper basis for removal due to Petitioner's forum state citizenship. 28 U.S.C. § 1441(b). In such a case, this Court has ruled that improper removal is a waivable (and, hence, a *non-jurisdictional*) defect. *Grubbs v. General Electric Credit Corp.*, 405 U.S. 699 (1972). Even under the court of appeal's conclusion, herein disputed, that "federal question" jurisdiction was lacking, it erred in assuming, per 28 U.S.C. § 1447(c), that the Respondents' cases had been "removed improvidently and without jurisdiction." (Emphasis added.) If "federal question" jurisdiction is unavailable, the suits were removed "improvidently" but the district court was *not* "without jurisdiction."

jurisdiction of the Food and Drug Administration, and the other "Bendectin" a drug made and sold in Canada under the governmental regulation of that country. "Debendox" is a distinct brand name pertinent to a drug manufactured in the United Kingdom by a British manufacturer and sold there by a subsidiary of the Petitioner.<sup>3</sup> The distinction between these brands of American and foreign drugs and the corporate separateness and differing nationalities of the concerns which produced and sold them, were obvious obstacles to the Respondents' plan to secure the benefits of an American forum and to participate in the American "Bendectin" litigation.

Mindful of the dismissal for *forum non conveniens* of virtually identical Scottish and Canadian claims, Respondents inaccurately asserted in their complaints that they had taken American Bendectin. After removal, in opposing dismissal on the basis of *forum non conveniens* and seeking remand, the Respondents disclosed to the court that they had taken "Debendox."<sup>4</sup> (Joint Appendix at 43.) Respondents added:

<sup>3</sup> Respondents note that, historically, there was occasional shipment of bulk drug from the United States to the United Kingdom to cover shortfalls in the local production of Debendox. This ceased in 1977 and Mrs. MacTavish's pregnancy did not begin until August 1978. The MacTavish Respondents have not attempted to demonstrate that Mrs. MacTavish took an American-made drug. In any case, it is "misbranding" of Debendox which is the federal violation at issue. If Mrs. MacTavish took a "misbranded" drug, it was misbranded in the United Kingdom and the relevance of U.S. law to the labeling and promotion of drugs in the U.K. for sale in the U.K. is still the issue of her claims.

<sup>4</sup> Of course, a Canadian drug named "Bendectin" was available to Mrs. Thompson in Canada. The Thompson complaint, however, treated the Canadian drug as American-made. But, in litigating the issue of *forum non conveniens*, Petitioner demonstrated by affidavit that Debendox and Canadian Bendectin were manufactured and "branded" in the United Kingdom and Canada and no contrary evidence was offered by Respondents. Apart from Respondents' misleading complaints, there is no contention or evidence in the record that the Debendox or "Bendectin" available to Respondents were made, promoted or "branded" in this country.

"Debendox is the British trade name for the anti-nausea morning sickness drug Bendectin manufactured by defendant Merrill [sic]." The clear implication of this statement is that Debendox, itself, was manufactured in the United States. However, this Court will search the record in vain for any direct assertion by the Respondents that the Debendox available to the U.K. Respondent, Mrs. MacTavish, was manufactured in the United States.

Once again, the verbal feint in which the Respondents engaged has to be appreciated. Debendox is a drug made in the United Kingdom by an unrelated British concern and sold there by the Petitioner's subsidiary. *Dowling v. Richardson-Merrell, Inc.*, 727 F.2d 608, 611 (6th Cir. 1984). This fact was well known to the Respondents since their counsel argued before the Sixth Circuit for the plaintiff/appellants in the *Dowling* cases three months after Respondents' complaints were filed. 727 F.2d at 609. The foreign origin of Debendox was undisputed in the *Dowling* cases. Debendox was (at times) of the same formulation as Bendectin and was marketed in the United Kingdom beginning in 1958.

It is undisputed that the Petitioner developed, tested and promoted American Bendectin in the United States and that the Canadian and British drugs are sold by Petitioners' related corporations in the foreign countries of their origin. However, there is no assertion in the record that the Canadian or British drugs were themselves promoted or "branded" in the United States. Clearly they were not sold here.

It is the British and Canadian (as well as American) drugs which the Petitioner is accused of "misbranding" in violation of the Food, Drug and Cosmetic Act.<sup>5</sup> Stripped of its semantic

<sup>5</sup> It was only in their motion to remand that Respondents acknowledged that their "misbranding" allegation pertained, not only to the drug available in the United States, but also to the foreign drugs available in their homelands. (J.A. at 44) If the drugs which Respondents claim to have taken were not "misbranded," they would have no standing to complain of the "misbranding" of drugs sold in this country.

camouflage, this is the contention which underlies the Fourth Cause of Action of each complaint, one which the Respondents contend is irrelevant to federal question jurisdiction.

Whether the Congress ordained that the Food, Drug and Cosmetic Act govern the "branding" of drugs which are sold in foreign countries is a federal legal question of great significance. Respondents effectively contend that this issue should be decided anew by each state court which tries a case brought by a foreign plaintiff who claims injury from a violation of such statute. Such state court decisions would go beyond the application of settled federal law and will break new ground of statutory interpretation.

## II. STATE COURT DECISIONS ON THE MEANING AND EXTRATERRITORIAL SCOPE OF THE FOOD, DRUG AND COSMETIC ACT WOULD EVADE THE ABILITY OF THIS COURT TO IMPOSE UNIFORMITY OF FEDERAL INTERPRETATION.

The Respondents do not dispute that, to prevail on their Fourth Cause of Action, they must demonstrate that the Petitioner violated the Food, Drug and Cosmetic Act by "misbranding" Canadian Bendectin and Debendox. They do not critique or even address the Petitioners' analysis of the elements of proof inherent in their accusation of the "misbranding" of these drugs. However, they seemingly dispute that their Fourth Causes of Action will require construction and interpretation of the Food, Drug and Cosmetic Act. Respondents contend that the issue whether the British and Canadian drugs violated federal law may be submitted to a state court jury without any interpretative instruction by the trial court. Say the Respondents: "In effect, all the court must do is to command the jury to determine whether the particular regulations at issue have been violated and, if so, whether the plaintiff's injuries are of the type which the regulation intended to avoid." (Respondents' Brief at 38.)

This argument of the Respondents is, in reality, the best argument for original federal jurisdiction over a claim of this kind.

In the Respondents' view, not even the state court itself, but, rather, *the jury*, must deliberate the purposes of the Food, Drug and Cosmetic Act, determine its *applicability* to foreign plaintiffs (and foreign drugs), evaluate the advertising and promotional program of Petitioner for compliance with the federal statute and regulations, and emerge with a verdict. Respondents do not attempt to reconcile this proposition with their argument that "the availability of review by this Court on *certiorari* is sufficient to protect the federal interest involved." (Respondents' Brief at 27.) They do not explain the manner in which this Court (or any court) could review and correct the jury room deliberations of each state court jury on the meaning and scope of this federal regulatory statute. Even the Common Pleas Court of Hamilton County, Ohio (where Respondents' cases originated), would have no means to impose local uniformity on the several juries which would hear cases of this type. The jurors themselves, were they aware of the concept of *stare decisis*, would have no means to know how other juries had interpreted the statute, and no way to follow such a "precedent," even were they so inclined. Every such decision of a jury would be *ad hoc*, and unburdened by what had come before. This may be the chief virtue, from Respondents' viewpoint, of a state forum.

Petitioner disagrees that a state court could submit the issue of claimed Food, Drug and Cosmetic Act violations to a jury without an initial judicial construction of the statute, that construction then to be applied to the facts as the jury finds them. A claim of negligence *per se* does not, as Respondents contend, merely pose a discretionary decision on whether the state should "borrow" a federal safety standard. The substantive law of the controlling jurisdiction determines what effect, if any, a statutory violation has on tort liability. This is not an *ad hoc* determination of the court or jury but the standing rule of law of the place whose law controls.<sup>6</sup>

<sup>6</sup> In the *Dowling* cases, the district court observed: "At this juncture,

However, the legal questions as to the statute's requirements (or even whether it pertains) are always governed by the law which gives the statute its force, in this case, that of the United States. Here, the federal legal questions are (1) does the statute even govern the alleged injurious actions of the Petitioner, the "misbranding" of drugs in foreign countries, (2) did Petitioner's actions violate the statute and (3) are Respondents among those whom the law was designed to protect. Whatever use the state court may make of the answers, the *questions* are federal.

### III. SUSTAINING "FEDERAL QUESTION JURISDICTION" OVER RESPONDENTS' CLAIMS WILL ONLY RECOGNIZE FEDERAL JURISDICTION OVER NON-FEDERALLY CREATED CLAIMS WHICH SHOW THE NECESSITY FOR CONSTRUCTION AND INTERPRETATION OF FEDERAL LAW.

In closing their brief, Respondents argue that recognition of federal jurisdiction over their claims will extend that jurisdiction to every non-federally created claim which requires for its adjudication the *application* of federal law. This is a pretended issue which ignores the important distinction between claims which merely rely upon federal law and call for the application of such law to disputed facts, and those which will require *construction and interpretation* of federal law. The former type of case is common; the latter is not.

In *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983), this Court acknowledged that federal jurisdiction over a claim not federally created would lie only where the resolution of such claim requires a decision on a *federal legal controversy*:

then, it appears virtually certain that the substantive law of the United Kingdom will govern the actions." 545 F. Supp. at 1136. See also *Vanderliet v. Richardson-Merrell, Inc.*, Case No. C-1-82-470, Order Granting Defendant's Motion to Dismiss on *Forum Non Conveniens* grounds (S.D. Ohio Apr. 13, 1984) re application of Canadian law.

As an initial proposition, then, the 'law that creates the cause of action' is state law, and original federal jurisdiction is unavailable unless it appears that some substantial disputed question of federal law is a necessary element of one of the well-pleaded state claims, or that one or the other claim is "really" one of federal law.

Even though state law creates appellant's causes of action, its case might still 'arise under' the laws of the United States if a well-pleaded complaint established that its right to relief under state law requires resolution of a substantial question of federal law in dispute between the parties.

463 U.S. at 13 (emphasis added).

The distinction between a federal legal controversy and a merely factual dispute to be governed by federal law is a crucial one which Respondents' "flood of litigation" argument completely neglects. Only an unusual case will present a claim which, though not federally created, requires resolution of a federal legal question.

Complaints are drafted to avoid the impression that the legal premise relied upon is novel or complex or would require an extension or modification of previous interpretation. Plaintiffs do not knowingly telegraph crucial legal issues to their opponents or to the court in their pleadings. Respondents' complaints illustrate this practice by blaming American Bendectin for injuries which they actually attribute to two foreign drugs. Whether this type of effort to avoid federal jurisdiction is entitled to achieve its goal is a distinct question, however. Most plaintiffs who desire a state forum can avoid overt reliance on a questionable federal legal proposition without such artifice. The best illustration of this fact is found in the numerous federal cases cited by both Petitioner and Respondents which discuss federal jurisdiction over non-federal negligence claims premised on federal safety violations.

These cases include *Moore v. Chesapeake & Ohio Ry. Co.*, 291 U.S. 205 (1934); *Crane v. Cedar Rapids & Iowa City Ry.*

*Co.*, 395 U.S. 164 (1969); *Andersen v. Bingham & G. Ry. Co.*, 169 F.2d 328 (10th Cir., 1948); *Boncek v. Pennsylvania Ry. Co.*, 105 F. Supp. 700 (D.N.J. 1952); *Dennis v. Southeastern Aviation, Inc.*, 176 F. Supp. 542 (E.D. Tenn. 1959); *Jacobson v. New York, N.H. & H.R. Co.*, 206 F.2d 153 (1st Cir.), cert. granted, 346 U.S. 895 (1953) (solely on the question of diversity jurisdiction), *aff'd per curiam*, 347 U.S. 909 (1954); and *Owens v. New York Central R.R. Co.*, 267 F. Supp. 252 (E.D. Ill. 1967).

As Petitioner acknowledges in its principal brief, these precedents found federal jurisdiction lacking over state-created claims premised on certain federal safety violations. However, none of the opinions identified a federal legal controversy, apparent from the complaint, upon the resolution of which any particular claim would depend. *Moore*, *Crane*, *Jacobson*, *Andersen* and *Owens* each involved negligence claims based on violations of the Safety Appliance Act, a prosaic statute which left little room (and certainly posed no obvious need) for judicial construction.<sup>7</sup> The Tenth Circuit in *Andersen* specifically relied upon the absence of an apparent legal controversy concerning the federal statute in denying jurisdiction.

Of course, every claim has some *potential* to turn on a federal legal issue, particularly if federal law is relied upon in a complaint. This is not enough to invoke federal original jurisdiction. It will be an unusual case in which the complaint

<sup>7</sup> Petitioners disagree with Respondents' contention that these courts engaged in a "balancing" of state and federal interests. Rather, all found "federal question" jurisdiction lacking over a state law claim because it was not federally created. They applied the "Holmes test" for "federal question" jurisdiction as a principle of exclusion. This was not necessarily because they were unmindful that a state-created claim could, nonetheless, "arise under" federal law, but because those state claims did not present a *federal legal controversy* requiring decision. Respondents, in fact, subtly ask this Court to validate the Holmes test as exclusive, stating: "When no federal right of action exists, issues bearing on the plaintiff's right to recover on such claims are important state concerns which should be left to be enforced by the state." R.B. at 30.

shows that plaintiff's claim depends on a favorable *interpretation* of federal law rather than its mere application.

The recognition of "federal question" jurisdiction over claims not federally created in *Franchise Tax Board* is not at odds with the cases relied upon by the Respondents. None of such cases even considers that a state-created claim might sustain "federal question jurisdiction," presumably because the facts and pleadings did not suggest the necessity of federal statutory interpretation in trial of these state-created claims.<sup>8</sup>

Respondents erect a strawman in warning that, under Petitioner's jurisdictional test, a complaint which *might* have relied upon a federal violation in support of a claim of negligence but did not explicitly plead the federal violation, would become removable because of that *potential* federal issue. Petitioner has never made such an argument and the "well-pleaded complaint" rule would deprive it of any validity. A complaint which does not explicitly rely on federal law cannot be a basis for federal question jurisdiction.<sup>9</sup>

<sup>8</sup> Respondents erroneously imply that the plaintiffs in *Guthrie v. Alabama By-Products Co.*, 328 F. Supp. 1140 (N.D. Ala. 1971), *aff'd per curiam*, 456 F.2d 1294 (5th Cir. 1972), *cert. denied*, 410 U.S. 946, *reh'g denied*, 411 U.S. 910 (1973), had argued that a state-created claim was necessarily dependent on the federal violation which they alleged. (R.B. at 21.) The plaintiffs in *Guthrie* relied solely on the premise of an implied and *federally-created* cause of action under the federal act in issue. The courts in *Guthrie* did not consider under what conditions a claim not federally created could "arise under" federal law nor did they anticipate this Court's analysis of this issue in *Franchise Tax Board*. In contrast, *Westmoreland Hospital Association v. Blue Cross*, 605 F.2d 119 (3d Cir. 1979), *cert. denied*, 444 U.S. 1077 (1980), discussed in Petitioner's initial brief at pages 42, 43, and 44, addresses precisely the instant questions.

<sup>9</sup> The only exception to this rule (and one not applicable here) is where the factual substance of a plaintiff's claim places it within an area preempted by federal law, such that the *only* available cause of action must be a federal one. As this Court noted in *Franchise Tax Board*, "a plaintiff may not defeat removal by omitting to plead necessary federal questions in a complaint. . . ." 463 U.S. at 22. Had Respondents refrained from *pleading* the federal violation, their cases would not have been removed to federal

#### IV. BECAUSE RESPONDENTS' FOURTH CAUSES OF ACTION NECESSARILY TURNED ON A FAVORABLE CONSTRUCTION OF THE FOOD, DRUG AND COSMETIC ACT, "FEDERAL QUESTION" JURISDICTION OBTAINED AS TO THEIR ENTIRE LAWSUITS. IT IS IRRELEVANT THAT RESPONDENTS ALSO ALLEGED ALTERNATE THEORIES OF RECOVERY WHICH WOULD NOT REQUIRE INTERPRETATION OF FEDERAL LAW.

The parties agree that Respondents cannot recover on their Fourth Causes of Action without demonstrating that the Petitioner "misbranded" Debendox and Canadian Bendectin in violation of the Food, Drug and Cosmetic Act. They also agree that Respondents' other causes of action are not dependent on any construction of federal law. Finally, they agree that the court of appeals considered the First and Fourth Causes of Action collectively and ruled that the possibility that Respondents might recover for "negligence" on their First Cause of Action precluded federal question jurisdiction over their cases. The parties are, however, directly opposed on the proper jurisdictional significance of the other causes of action which do not invoke federal law.

Respondents and Petitioner concur that the decision of this Court in *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983), must be dispositive, but they disagree as to the meaning of that decision. Respondents focus, as did the court of appeals, on their potential for recovery for "negligence" on their First Cause of Action which did not invoke federal law. Though they also dispute the sufficiency of the federal issues inherent in the Fourth Cause of Action to sustain jurisdiction, Respondents maintain that, in any case, such federal issues are not necessary to their "right to relief." The parties, therefore, call upon this Court

court. The hypothetical case where no federal issue is pled has no relevance whatever to the instant situation.

to decide in what sense a federal issue must be "necessary" or "essential" to a plaintiff's case in order to render that case one "arising under" federal law.

For reasons unknown, neither the court of appeals nor the Respondents point out the potential for recovery on their claims for strict liability, breach of warranty or "fraud and deceit upon the consuming public . . ." (J.A. at 23, 33). If the First Cause of Action renders the federal violations "non-essential," all the other concededly non-federal<sup>10</sup> claims do so as well. All allege the same injuries and, thus, in the broadest sense, all concern the same "cause of action," and the same "right to relief." If the Respondents' position be adopted by this Court, a plaintiff may pose even the most difficult, novel or important federal questions in a claim which will require their resolution, and yet anchor his lawsuit firmly to the state court merely by pleading alternate grounds for recovery which do not require such resolution.

Respondents cite to this Court's decision in *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1920), and distinguish it from their cases on the ground that the plaintiff therein relied solely on his allegation that the congressional acts in issue were unconstitutional, raising no non-federal ground for relief. The acid test of this distinction is to postulate a parallel state ground for relief in the *Smith* case and examine the result which the Respondents' legal proposition would produce. Had the plaintiff in *Smith* also pled some non-federal ground to enjoin the investment in farm loan bonds, his claim, say Respondents, would be beyond federal original jurisdiction. Adoption of the Respondents' position in this hypothetical case would confer *exclusive* original jurisdiction on the state court to adjudicate the federal constitutionality of an act of Congress. This bizarre result would proceed from the plaintiff's decision, not to refrain from reliance on federal

<sup>10</sup> Petitioner does not concede that these claims are "state-created" claims. Their dismissal on grounds of *forum non conveniens* presupposed that United Kingdom and Canadian law would control.

late, but that he would also rely on state law. It is illogical that federal question jurisdiction be extinguished by the parallel pleading of non-federal grounds for relief.

Petitioner, in its principal brief, recalled this Court's several pronouncements in *Franchise Tax Board* which paraphrased the elements of "federal question" jurisdiction over claims not federally created. The court of appeals fixed upon the language which declared that such jurisdiction required that the substantial federal issue be an "essential" and "necessary" element of plaintiff's "cause of action" or his "right to relief." However, the court of appeals overlooked the explicit acknowledgement of this Court that such a "federally dependent" state law claim could confer subject matter jurisdiction *though other state law claims were also pled*. This Court stated:

As an initial proposition, then, the "law that creates the cause of action" is state law and original federal jurisdiction is unavailable unless it appears that some substantial, disputed question of federal law is a necessary element of *one* of the well-pleaded state *claims*, or that *one* or the other claim is "really one of federal law."

463 U.S. at 13 (emphasis added).

This Court used the same disjunctive analysis of the causes of actions in specifically addressing the complaint at issue in *Franchise Tax Board*:

Simply to state these principles is not to apply them to the case at hand. Appellants Complaint sets forth two "causes of action," one of which expressly refers to ERISA; if *either comes within the original jurisdiction of the federal courts, removal was proper as to the whole case*.

463 U.S. at 13 (emphasis added).

In seeking to distinguish this Court's individualized treatment of the causes of action in *Franchise Tax Board*,

Respondents confuse this Court's usage of the phrase "cause of action" and "right to relief" in *Franchise Tax Board* with the definition of "cause of action" applied in *Baltimore SS Co. v. Phillips*, 274 U.S. 316 (1926), with reference to the doctrine of *res judicata*. *Baltimore v. Phillips* defined "cause of action" as the general right to relief for a single injury, regardless of the multiplicity of legal theories or factual allegations which might support that "cause of action." By that definition, *Franchise Tax Board* presented three causes of action, one for each of the unpaid tax levies. By the same analysis, Respondents' complaints each present three "causes of action," i.e., one for each parent and child. Clearly, *Franchise Tax Board* used "cause of action" to mean something other than "actionable injury." In a jurisdictional decision, headings placed on pleadings and broad textbook classifications of tort theories such as "negligence" are of little use in determining whether a "cause of action" has the necessary "federal" character. The question must always be whether the plaintiff has relied upon federal law as a distinct basis for recovery so that the federal legal questions will actually be litigated by the parties.

*Franchise Tax Board* recognized that claims based purely on non-federal law were subject to pendent federal jurisdiction if joined with factually related claims as to which "federal question" jurisdiction exists. This recognition was extended to any type of claim arising under federal law, whether because federally created or because of an essential federal element.

In *United Mine Workers v. Gibbs*, 383 U.S. 715 (1966), this Court noted the error of limiting pendent jurisdiction based on an outmoded concept of "cause of action":

This limited approach is unnecessarily grudging. Pendent jurisdiction, in the sense of judicial power, exists whenever there is a claim "arising under [the] Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority . . .," U.S. Const., Art. III, § 2, and the relationship between

that claim and the state claim permits the conclusion that the entire action before the court comprises but one constitutional "case." The federal claim must have substance sufficient to confer subject matter jurisdiction on the court. *Levering & Garrigues Co. v. Morrin*, 289 U.S. 103. The state and federal claims must derive from a common nucleus of operative fact. *But if, considered without regard to their federal or state character, a plaintiff's claims are such that he would ordinarily be expected to try them all in one judicial proceeding, then, assuming substantiality of the federal issues, there is power in federal courts to hear the whole.*

383 U.S. at 725 (emphasis added).

The court of appeals read *Franchise Tax Board* as excluding a claim which is dependent on an essential federal issue from this rule of law because the potential for recovery on other non-federal claims renders the federal issue non-essential. It overlooked the principle that a claim may be "federal," though not federally created. Respondents' Fourth Causes of Action are "federal claims." Their non-federal claims do not destroy this jurisdictional foundation but are rather subject to the federal jurisdiction so founded.

#### V. THERE IS A SUBSTANTIAL FEDERAL INTEREST IN SECURING THE UNIFORM INTERPRETATION OF THE FOOD, DRUG AND COSMETIC ACT AND IN LIMITING THE ACT'S PROHIBITIONS TO THOSE WHICH THE CONGRESS INTENDED.

Respondents assert that the application of the Food, Drug and Cosmetic Act by an Ohio court is a matter of chiefly local concern which will not impede the regulatory functions of the Food and Drug Administration. This erroneously assumes that the legislative intent behind a federal statute cannot be frustrated by an overly expansive interpretation of its provisions. It is true that a state may enact local laws which are

more restrictive than their federal counterparts in regulating the pharmaceutical industry. Such local laws, however, do not attempt to govern conduct beyond the borders of the state which enacts them. In contrast, state court judgments founded on claims of federal violations will impact the regulated industry beyond the borders of the forum state. When such judgments concern nationally or internationally marketed products, every plaintiff's recovery is a clarion call to other plaintiffs to sue on similar grounds. The call is nationwide and world-wide. This Court's writ of certiorari cannot, as a practical matter, tuck the bugle call back into the bugle. This nationwide impact of a federal law is a matter of proper federal concern.

In arguing the legislative history of the Food, Drug and Cosmetic Act, Respondents overlook the fact that a provision for a private right of action, expressly included in an earlier version of the bill, was omitted out of congressional concern that existing state defenses for drug product liability *would be curtailed* by such an enactment.<sup>11</sup> The Hearings on Senate Bill 1944 (74th Congress) produced opposition to a provision in the pending bill creating a private right of action for violations. Among the arguments advanced was the fear that such provision would curtail previously available state law defenses to such claims. Secretary of Agriculture Wallace stated:

Why, therefore, encumber a United States statute with such a provision when an injured party already possesses an adequate remedy which can be pursued in the state courts?

<sup>11</sup> Respondents egregiously mischaracterize their Fourth Causes of Action in asserting that they rely upon the alleged federal violation only in anticipation of Petitioner's defenses. Unless they prove the federal violations which they allege, Respondents' Fourth Causes of Action would be disposed of by directed verdict at the conclusion of Plaintiffs' case. Obviously, the federal violations are an essential part of Respondents' *case-in-chief*. This is why the Respondents devoted a separate section of their complaints to such violations.

The new provision, if enacted, would only be an invitation to blackmailing claims and suits.

At common law the defendant in a damage suit would have the right to plead contributory negligence and to show that the injury complained of was due primarily to the negligence of the plaintiff. That he would have such right of defense under this bill, if enacted, is not entirely certain.

Foods, Drugs and Cosmetics; Hearings on S. 1944 Before A Subcommittee of the Committee on Commerce, U.S. Senate, 74th Cong., 2nd Sess. (1933), Statement of Henry A. Wallace, Secretary of Agriculture.

The Food, Drug and Cosmetic Act is, through its regulatory provisions, a restraint on commerce. It is as much an objective of the Act to *define* that restraint as to enforce it. Though state law may properly attach local tort law consequences to federal violations, the objectives of Congress may be as readily thwarted by a state court's erroneous expansion of the Act's prohibitions, as by a drug company's violation of them.<sup>12</sup>

The American pharmaceutical industry is the most exposed, by its nature, to the risk of a stampede of product liability lawsuits, with the profoundly adverse financial consequences *apart from liability* which comes with such a stampede. It is as important an objective of the Food, Drug and Cosmetic Act that safe and efficacious drugs move in interstate commerce without undue hinderance, as that injurious drugs be interdicted. Neither of these objectives, merely at a plaintiff's election, ought to be entrusted to the *exclusive* original jurisdiction of state courts.

<sup>12</sup> This is especially true where, as here, the federal agency charged with enforcing the Act has given its approval to a drug product in advance of marketing, and the civil tort suit will occasion a *de facto* review of that agency decision by the state court.

Cincinnati, Ohio 42303  
211 Walnut Street  
3100 Fountain Square Plaza  
DIZMOBE & ZHONG  
Christine L. McBroom  
John E. Schlosser

Of Counsel:

Counsel for Petitioner  
(213) 822-8300  
Cincinnati, Ohio 42303  
211 Walnut Street  
3100 Fountain Square Plaza  
Frank C. Woodside III  
Respectfully submitted,

Dated: April 12, 1988

cont.

Circuit with directions to affirm the judgment of the district  
mandated to the United States Court of Appeals for the Sixth  
the court of appeals should be reversed and the case re-  
EC, the reasons stated in this reply brief, the judgment of

### CONCLUSION

meanwhile.

interpretation cannot undo the damage which occurs in the  
ability of this Court to correct state court errors of federal in-  
in an era of mass tort litigation, the unavoidably delayed  
may easily dwarf the restraints which the Congress intended.  
court interpretations of the Food, Drug and Cosmetic Act

The potential impact on the drug industry of adverse state